

Soy Information Network

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WELCOME

Welcome to the Soy Information Network and to its first newsletter. The network has been set up by concerned scientists, parents and citizens to provide information on soy products that the soy industry and the Ministry of Health are reluctant to provide.

In a later article we set out the basis of our concerns about soy infant formula. In later newsletters we will provide more information and an opportunity for you to express your own opinions.

At this early stage we are gathering information to assist in any enquiry that may result from our suggestion that research into the long term effects of soy infant formula is required. Initially we need to get a feel for the range of experiences that people report so that we can design a questionnaire which covers the ground properly. We are grateful for your contribution to this pool of information.

We are interested in receiving details of your particular experience, especially with soy infant formula. If we receive such information from you we undertake to treat both the information and your own details with complete confidentiality. Personal information will not be released. If a media representative wants to contact members of the network, we will write to you and invite you to contact the particular reporter. In this way you, and only you, will be in control of whether contact is made. If it becomes apparent that particular symptoms are appearing regularly, we will give a generalised account in a newsletter without divulging personal details.

There are at least two broad groups of users of soy infant formula:

1. Those whose infants are unable to tolerate cow's milk formula for some reason. If your child was/is in this category, please tell us how your child's problem was diagnosed.

2. Those who choose to use soy formula for some reason other than a diagnosed allergy or intolerance. If your child was/is in this category, please tell us why you chose to use soy formula.

If you still have Plunket records of your infant's feeding regime, please let us know. The existence of such records may be of great value if an epidemiological study is undertaken in the future. Please note that we are interested in hearing from you whether your experience of soy formula was good or bad.

Feel free to share the information in this newsletter with your friends and invite them to write to us if they wish to become a member of the Soy Information Network.

If you would like to assist with a donation towards our costs please send a cheque made out to "Soy Information Network". Thank you.

NZ SCIENTISTS TO ATTEND INTERNATIONAL CONFERENCE ON PHYTOESTROGENS IN DECEMBER

Two New Zealand scientists will be attending the Third International Conference on Phytoestrogens in Little Rock, Arkansas, from December 3 to 6. Dr Mike Fitzpatrick, the independent consultant who prepared the reports which revealed the potential for problems with soy products, and Professor Cliff Irvine, a reproductive endocrinologist at Lincoln University, will both be at the conference to present an invited paper on the soy infant formula issue to this scientific forum. The Conference is organised and sponsored by the Division of Reproductive and Developmental Toxicology, part of the US Food and Drug Administration's National Center for Toxicological Research.

The Conference lasts for two and a half days and one and a half days are to be devoted to papers exploring the benefits and the risks of dietary phytoestrogens. The wide publicity which has resulted from the New Zealand work has caused a great deal of interest in this conference and a number of scientists from around the world will be attending. We understand that the soy industry will also be present in force. We hope to present some notes from the conference in the next SIN Newsletter.

SOY INFANT FORMULA: THE QUESTION

The following article sets out the basis of the concerns of those who have been involved with the attempt to have soy infant formula removed from general sales until an

epidemiological study has been carried out. We believe that the mothers of young infants have a right to this knowledge so that they can exercise an informed choice.

When we first approached the Ministry of Health a year ago and gave them the results of our analyses of soy infant formulas, together with the results of our search of the scientific literature, we expected that this would start a scientific debate and would trigger research that would reach some sort of conclusion within a year or two.

We also expected that mothers would be warned by the Ministry that soy infant formula contained certain substances derived from soy beans which are not normally present in a baby's diet when fed on breast milk. There are several of these substances but the ones we emphasised to the Ministry are called *isoflavones*. Because of their estrogenic effects in animals they are also called *phytoestrogens*, which means "estrogens derived from plants". These substances are able to occupy the sites in cells which are normally available to hormones generated within the infant's body, hormones that influence how these cells develop. Although the isoflavones are very much weaker than the natural hormones, they are present in soy formula [and many other soy products], at very much higher concentrations. The higher concentration may cancel out the effect of them being weaker.

Unfortunately, the Ministry did not give this warning. This means that people are buying and using soy infant formula without full knowledge of what they are buying. It is also unfortunate that the research that is essential to determining whether soy infant formulas are safe in the long term has not been started. The Plunket Society was planning an investigation earlier this year but their plans were disrupted by the denial of research funds by the Ministry of Health. Research funding is being sought currently by about three people or groups of researchers that we are aware of but to date none has been awarded.

The Argument:

Our argument is quite straight forward:

- Recent research at Cambridge University shows that when women who have not yet reached menopause eat soy protein at normal dietary levels [60g soy protein per day], the isoflavones in the diet have a marked effect their menstrual cycle and on the hormones that trigger ovulation. The menstrual cycle was lengthened by 1½ days and the two main ovulation hormones were reduced to a half and a third of their levels before the soy diet was started. This means that the soy isoflavones are biologically active in humans at dietary levels, a fact which was not known directly before this work was done. The

amount of isoflavones in the diet of these women was 45 milligrams per day; their average weight was 64 kilograms, so the dose rate was 0.73 mg isoflavones per kg body weight per day. They were on the soy diet for 30 days [one menstrual cycle] and it took up to three months for the effects to wear off. The validity of this research is widely accepted by scientists on both sides of this debate.

- There are four soy infant formulas on sale in New Zealand: Prosobee, Infasoy, Karicare and Isomil. Our analysis shows that they contain around 150 mg [range 177 to 125] of isoflavones per kg of dry formula. When the formula is made up as directed and fed as recommended on the labels on the cans, a baby will consume a dose of around 10 mg isoflavones per day during the first month of its life, rising to about 20 mg per day at four months and older. When these consumptions are converted to a dose rate, by dividing the dose by the approximate weight of the infant at these ages, we find that they are consuming about 2.5 mg per kg body weight per day at one month of age and 3.5 mg/kg/day at four months. These dose rates are 3.5 to 4.8 times higher than the rates which caused the changes in the women's menstrual cycles when fed to them for 30 days. However, babies may be fed this formula for up to six months as the sole source of nourishment and for much longer than that as part of a more diverse diet. The validity of these analyses can easily be checked in any competent laboratory having the right equipment and the appropriate pure isoflavone standards. The analyses are in line with those reported by other scientists. The dose rate calculation is, we believe, novel, in that we have not seen it reported elsewhere. However the calculation is simple and straightforward.
- The argument at this point is more speculative because the facts are not available. Babies are growing and developing and are thus more likely to be at risk from interference from unusual estrogenic substances. They are also less likely to have developed the biochemical mechanisms necessary to detoxify foreign substances that evolution has not prepared them for. The difficulty is that developmental problems may not become apparent for many years, perhaps at puberty or beyond, and it is unlikely that problems observed at that stage of life will be related back to the infant feeding regime.

Those are some of the facts and considerations that we thought mothers had a right to know before they decided to feed their baby on soy formula, especially those mothers whose infants are not diagnosed as being allergic or intolerant of cow's milk formula. The Ministry and the soy formula manufacturers think otherwise.

Put very simply, we have asked the following question:

"If the soy phytoestrogens, as part of a diverse diet, have this marked effect on women's menstrual cycles at a dose rate of 0.73 mg per kg body weight per day for 30 days, what will the effects be on infants who consume 2.5 to 3.5 mg per kg per day for six months when soy formula is their total diet?"

We are still waiting for an answer.

WHY FEED SOY FORMULA TO INFANTS?

There are several reasons why a mother might choose to feed soy formula to her baby. The usual reasons are:

- Because she believes her child is allergic to dairy protein;
- Because she believes her child is intolerant of lactose;
- Because she believes soy formula is more healthy than dairy formula.

Protein Allergy:

As far as we can determine, something less than 5% of infants [and less than 1/2% of adults] have a genuine allergic response to dairy protein. Of these about a quarter to a half are also apparently allergic to soy protein. Children tend to outgrow milk allergy by the time they are 3 years old. Given the possibility of problems with soy formula, we would advise a prudent mother who suspects that her child is allergic to one of the cow's milk proteins to get a positive diagnosis of this through her doctor or through Plunket and to have the baby checked for sensitivity to soy protein at the same time. It is all too easy to assume that a problem is due to an allergy and not to check it out. There are several non-soy options for getting around allergenicity to a specific dairy protein. Your doctor should be able to advise you on these if you make it clear that you would prefer not to use soy. The options include formula based on goats' milk, formula based on cows' milk which has had some of the proteins removed and formula made from hydrolysed dairy protein. [The allergic reaction depends on the shape of the protein molecule. When proteins are hydrolysed they are broken down by enzymes to the stage where the shape that causes the allergic reaction is no longer present.] There may be some flavour problems with the hydrolysed product and it is more expensive. In a case of need it may be possible to get a subsidy - ask your doctor.

For a more extended discussion of milk allergy we recommend that you write to the Dairy Advisory Bureau, PO Box 417, Wellington for their short publication "Milk Allergy - Is it an issue for you?" This includes information on lactose malabsorption and was prepared with the assistance of independent advisors.

Lactose Intolerance:

After watching the TV advertising for certain soy products, one could be forgiven for believing that lactose is some sort of insidious evil compound lurking in cows' milk. It isn't. Lactose, or milk sugar, is the main carbohydrate in the milk of almost every one of the mammal species on earth for which the composition is known. The only exception

we are aware of is the sea lion. Presumably there are evolutionary advantages in a mother providing her infant with lactose rather than some other sugar. It has been known for many years that lactose in the diet has a favourable effect on calcium absorption, especially in infants, and there are numerous other beneficial physiological effects known.

We understand that the incidence of real [primary] lactose intolerance in babies is very rare. It is not an allergy. It is caused by the inability of the cells lining the intestine to make the particular enzyme needed to break down the lactose into its two constituent sugars. If you suspect that your baby is intolerant of lactose, you should have your doctor check it out specifically.

Not so rare is a temporary [secondary] intolerance of lactose following a gastric infection that has damaged the lining of the baby's intestine. Use of a low lactose formula for a short period allows the gut to heal and to regain the ability to make the needed lactase enzyme. If you suspect that your baby is lactose intolerant, you should consult your doctor for a positive diagnosis.

Because it is Healthy:

Over eons of progressive development human breast milk has evolved as the most suitable food for the human baby and human babies have evolved to make the best use of it. Human breast milk is the "gold standard" of infant feeding and is preferred over all substitutes.

The primary alternative recommended by the Plunket Society is a formula based on cows' milk. A properly designed formula is very similar in overall composition to human milk. The protein content is reduced with respect to the level in cow's milk. The ratio of the whey proteins to the casein proteins is increased. The lactose content is substantially increased to match the level in human milk. The mineral and vitamin contents are adjusted. Some of the more sophisticated formulas, especially in Japan, have the fine makeup of the fat adjusted and may have specific enzymes and oligosaccharides added to simulate human milk more closely still. But we are still far from understanding in detail the purpose of some of the minor constituents of human milk. In fact it is probable that researchers have not yet even identified all the biologically active components of human milk. Even so, reasonably close simulation of human breast milk starting from cows' milk is possible as the basic building blocks, the proteins, fat, lactose and minerals are the same or very similar.

Over eons of progressive development the soy bean has evolved as the most suitable way for the soy plant to reproduce itself. It may well be that the evolutionary advantage that the phytoestrogens confer on soy beans is their ability to adversely affect the

reproductive health of their predators. The phytoestrogens in subterranean clover are certainly capable of causing permanent infertility in some sheep.

In choosing to feed a baby on soy formula for reasons other than confirmed allergy or lactose intolerance, a mother is choosing not to provide the child with most of the particular natural substances that are in human milk as a result of evolution and natural selection. Are we so sure that we know enough about infant development to say with confidence that we know better than nature what an infant needs?

CONCLUDING REMARKS:

We have asked a question about the long term developmental effects of feeding soy phytoestrogens to infants. The answer is not known. If only a small proportion of soy formula children are affected and the effects are only observed in later life, it is not likely that a connection with soy consumption will be made. If your child has a problem, we suggest that you ensure that your doctor is aware that your child was raised on soy formula. In this way, if there are connections with particular conditions or symptoms, they will eventually come to the attention of the health system. To assist you in this we enclose a copy of the letter that four of the scientists who are familiar with the soy work wrote to the NZ Medical Journal earlier this year, together with a resulting summary of the letter in MedAlert.

OTHER ENCLOSURES:

We are also enclosing cuttings of some recent articles in newspapers. The first is copied from "The Times" of London and is an interview with Dr Richard Sharpe of the UK Government's Medical Research Centre for Reproductive Biology.

The remaining articles are from the NZ Herald, written by Camille Guy. The first of these articles was branded by soy industry representatives as "irresponsible journalism" at a news conference held during the Nutrition Society's conference in late August. However, on 14 October they won first prize and \$4000 in the "Food News" category for Camille Guy at the NZ Guild of Food Writers Annual Conference.

The final page contains three of the letters to the NZ Herald which resulted from the Symposium on Phytoestrogens at the Nutrition Society's Annual Conference.

In an uncopied letter to the Herald, replying to the letter from Trevor Johnston, Dr Pat Tuohy, the Director of Policy for Plunket wrote:

"It would be incorrect to say that the Plunket Society endorses the safety of soy infant formula. Our official position is that there is no evidence that the product is harmful to babies, but we do not endorse its use."

Finally, in response to the letters in the Herald from both Trevor Johnston and Professor Tasman-Jones, we would like to emphasise the following point, which was made very clearly at the Symposium as well:

The issue of toxicity in parrots [found by at least 35 parrot breeders, not just one] is not relevant to our argument about soy infant formula. There is no "leap of logic" from bird food to soy formula and no calculation has been made based on the "unproven hypothesis that soy oestrogen-like substances caused the illness and death in parrots". The problems with the parrots led us to look closely at the scientific literature on the toxic or anti-nutritive compounds in soy beans. As was demonstrated earlier, our calculations have been based on the demonstrated fact that soy estrogen-like substances cause measurable disturbances to women's menstrual cycles. This fact proves that these substances are physiologically active in adult humans. The effects on parrots are irrelevant.

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