

Soy Information Network

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EDITORIAL

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In 1992 the United Kingdom's Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment, generally known as COT, recommended that levels of phytoestrogens in soy formulae and other soy foods for children should be analysed, monitored and exposure data obtained. In January 1995 Sue Dibb, Co-director of the Food Commission in London, wrote to the UK Ministers of Health and Agriculture to express concern that this research was yet to start and urging them, in view of the work here in New Zealand, to give the matter urgent priority. Baroness Cumberlege, the UK Parliamentary Under Secretary of State for Health, advised that the Ministry of Agriculture, Fisheries and Food (MAFF) had already commissioned further research into the subject in the 1995/96 financial year and that COT would review the results when they were available. This was later confirmed by the Minister of Agriculture, Fisheries and Food.

On 17 July last Sir Kenneth Calman, Chief Medical Officer of the [UK] Department of Health, activated the Public Health Link to send a detailed message on phytoestrogens to around 60,000 health professionals. On the following day the UK Department of Health held a press briefing and released copies of the COT statement on the issue, and of the message they had sent out on the Public Health Link, to the press and to the soy formula industry.

This issue of the SIN Newsletter reprints both documents in full, together with the Patient Information Leaflet also released by the UK Department of Health on the Public Health Link. Also included are reprints of media statements by the [UK] Food Advisory Committee, the NZ Ministry of Health and the Soy Information Network. Copies of some UK and NZ press coverage are also provided.

We have taken this action to demonstrate how the NZ MoH Media release watered down the COT statement to the extent that the warning: *"The potential for phytoestrogens, including isoflavones, to affect adversely infants is of particular concern since it is possible that a hormonal imbalance in early life can permanently affect sexual development and fertility"* was completely omitted, thus subverting the intent of the COT statement. The MoH release (and the original COT message) was then further distorted by the magazine "Healthy Options" resulting in the proclamation on their cover, "Soy Milk Declared Safe!" and in the related headline, "Soy Milk Safe: Ministry of Health Media release". About half of the content of their article under the above headline consists of material which was not drawn from the MoH release some of which is factually wrong.

We understand the the Ministry “has made a formal complaint about its [Healthy Options’] misrepresentation of Ministry of Health advice to consumers about soy milk” and has requested them, “...to acknowledge this misrepresentation and reprint our media release in full”. The Winter issue of Vegan Voice also got the wrong impression from the MoH media release, headlining their Stop Press “Soy Joy”, but at least they reprinted the release in full for their readers. The Soy Information Network has made a formal complaint to the Ministry of Health about their own misrepresentation of the COT warning. Watch this space for their response.

It is disappointing that the COT statement does not report any data from the much heralded MAFF-sponsored research. The concentrations of phytoestrogens in [UK] soy formulae and infant foods won’t be available until some time next year.

However, the COT statement voices the same concerns that the Soy Information Network has been publishing and which have been repeatedly taken to the NZ Ministry of Health since November 1994. In fact when I first put the matter before the MoH I expected that they would advise health professionals in New Zealand in much the same way as has been done in the UK.

SIN opinion still differs from those of the UK’s DoH and the NZ MoH in that we consider that soy formula should be available **only on prescription** until the urgent research called for by COT is complete, and we have often written to the Ministry and Minister of Health to this effect. The NZ Ministry’s Press Release on the COT statement refers only to the advice that “*..if your doctor or health professional has recommended that you feed your baby soy based infant formula, you should continue to do so.*” and says that the results of a literature review “*..show from current evidence there are no adverse health effects from soy infant formulas.*” SIN has requested a copy of this literature review under the Official Information Act. However, for comment on the “no adverse health effects” claim read the article “THERE ARE NO REPUTABLE STUDIES...” on page 16.

But we ask the MoH again: **“What are you doing to ensure that parents who feed soy infant formula to their baby without medical supervision are fully informed of the potential risks identified by the Fitzpatrick and the COT reports?”**

NZ Herald Coverage of COT Report Questioned

The strange behaviour of the NZ Herald calls for comment. On 19 July a short article on the COT statement (see attached copy) was published in their first edition, the edition that is destined only for rural and out of town distribution. This article did not run in succeeding editions. Thus nobody in the Auckland Metropolitan area was advised by the Herald that the safety concerns about soy formula raised by SIN and others were shared by the UK Department of Health’s committee of independent experts, COT. Considering the coverage given to the soy formula controversy over the last year by this paper, one would have thought that this independent vindication of their editorial stand would have been given some prominence.

Is this unilateral decision to deny people the right to know the results of an independent study of soy infant formula concerns related in any way to pressure from a local soy food manufacturer, the one who harassed Dr Mike Fitzpatrick’s employer a year ago

and had Mike prevented from presenting his scientific paper at the Little Rock Conference? (See "Gag the Messenger" in SIN Newsletter #2.)

**STATEMENT BY THE [UNITED KINGDOM] COMMITTEE ON THE
TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND
THE ENVIRONMENT**

Released 18 July 1996

Phytoestrogens

Phytoestrogens are widely distributed plant chemicals which can cause oestrogenic effects.

Two of the main classes of phytoestrogens are the coumestans and the isoflavones. They are capable of binding to the oestrogen receptor but in many tests *in vivo* and *in vitro* are considerably less potent than androgenous oestrogens. Because of the differences in efficacy and in binding affinities to the oestrogen receptor and the dependence on the intrinsic oestrogenic state (ie prepubertal, premenopausal, postmenopausal) of the target tissue, either agonistic or antagonistic responses can be produced (1-5).

Phytoestrogens have been shown to cause infertility in animals, the first cases being noted in ewes which became infertile, less sexually receptive and more aggressive. The infertility syndrome, named *Clover Disease*, was subsequently discovered to be caused by high concentrations of coumestrol (a coumestan) in the clover grazed by the sheep (2, 6-8). In laboratory animals, exposure to coumestrol via dams milk has also been shown to cause effects on oestrous cycling, LH response following oestrogen and progesterone priming, and behaviour which only became apparent as the animals reach sexual maturity. Furthermore, administration of phytoestrogens to these same species can cause androgenisation of females and feminisation of males, although the effects vary according to time and duration of intake (9-14).

At present, there are only limited data on the intake of phytoestrogens in specific population groups in the UK. People consuming an Asian diet and vegetarians have high intakes of soy, a major source of isoflavones (4, 15-20). The isoflavones found in plant material are mainly bound to sugar residues and are inactive (2, 21). The active aglycones are released in the gastro-intestinal tract by gut microflora and are subsequently absorbed and metabolised (2, 22). Known differences in the microflora between people consuming a Japanese diet and those consuming a Western diet could result in differences in the effects of isoflavones in these different population groups (23). Human studies have also indicated that there is inter-individual variation in the metabolism of daidzein, one of the isoflavones found in soy. Approximately 30% of the population is able to metabolise daidzein extensively to equol, while the majority of the population produce smaller amounts of this metabolite (24). Phytoestrogen excretion has also been reported in a small study in male infants fed either human milk, cows' milk formula or soy-based formula from birth to 4 months of age (25). Total urinary isoflavonoid concentration was approximately 20 microgram per litre ($\mu\text{g/l}$) for the infants fed human milk, 100 $\mu\text{g/l}$ for the infants fed cows' milk formula and 600 $\mu\text{g/l}$ for the infants fed soy-based formula. Of the three isoflavones determined, only daidzein

and genistein were detected, with the concentration of equol being minimal in all groups.

Consideration of phytoestrogen toxicity and subsequent risk to certain groups of the population is complex since their actions are tissue and end-point specific and depend on the developmental and maturational context in which they are assessed. The complexity is further compounded by differences in metabolism as outlined above.

In preliminary studies in premenopausal women normally consuming a Western diet, ingestion of soy protein (60g per day for one month, equivalent to 0.73 mg isoflavones/kg bw/day) has been shown to suppress mid-cycle peaks of LH and FSH and significantly increase the duration of the follicular phase (26, 27). The effects lasted for up to 3 months following the termination of soy consumption. There are reports that phytoestrogens can reduce blood cholesterol (25, 26, 28, 29), and that they may protect against osteoporosis and reduce flushing in postmenopausal women (29, 30). Epidemiological evidence from adult populations which habitually ingest high quantities of soy (eg, Chinese and Japanese) suggest that these individuals have a lower incidence of some types of cancer (4, 15, 18, 28, 29). However, it is difficult to resolve the effects and consequences of other dietary variables such as fibre, vitamins, fruit, vegetables and meat when considering the validity of this observation. The subject of dietary constituents and cancer is presently under review by a Working Group of the Committee on Medical Aspects of Food Policy (COMA).

The potential for phytoestrogens, including isoflavones, to affect adversely infants is of particular concern since it is possible that a hormonal imbalance in early life can permanently affect sexual development and fertility. Such effects have been observed in a number of animal studies (2, 4, 9-14). We are not aware of any reports which suggest that populations which habitually ingest high quantities of soy (eg Chinese, Japanese) have impaired fertility or altered sexual development. Limited data indicate that the estimated intake of isoflavones by infants fed soy-based formulae is in the region of 4 mg/kg bw/day (31, 32). This is higher than the intake reported to cause hormonal effects in premenopausal women (approximately 0.73 mg/kg bw/day). Since we do not have data specifically relating to the potential effects of soy phytoestrogens in human infants, particularly in those whose mothers normally consume a *Western* diet, we *recommend* that research should be undertaken as a matter of high priority to determine whether ingestion of soy based formulae carries any risk for infants. (See Annex A for list of recommended research proposals). As a result of further research, it may be necessary to consider the potential risk of soy products to other sectors of the population. We *endorse* the advice of the Department of Health that breast milk and cows' milk formulae are the preferred sources of nutrition for infants. However, women who have been advised by their doctor or other health professionals to feed their baby soy-based formulae should continue to do so. The Committee on Medical Aspects of Food Policy has published a more detailed report of the preferred sources of nutrition for infants (Department of Health. Weaning and the Weaning Diet. London: HMSO, 1994. Report of Health and Social Subjects: 45).

July 1996

ANNEX A

Recommended research proposals listed in order of priority

1. Investigation of the bioavailability and excretion of isoflavones in infants.
2. Determination of the phytoestrogen content of breast milk from mothers habitually ingesting soy and follow up infants.
3. Consideration of the differences between the UK population and those habitually ingesting soy (eg Japanese, Chinese), ie differences in gastric microflora, genetic variability in metabolism and possible adaptation to soy. Consideration of the possible differences in bioavailability and other physiological effects between extensive and non-extensive equol producers.
4. Re-evaluation of the literature on populations exposed to large quantities of soy to look for evidence of harm.
5. Re-evaluation of reports on potency and of oestrogenic/anti-oestrogenic physiological effects of phytoestrogens with a view to establishing an equivalency factor approach.
6. Investigation of the effects of isoflavones on the development of the rat (oral administration).
7. Studies to provide information on absorption, distribution, metabolism and excretion of isoflavones in the rat. Determination of tissue distribution and *in vitro* metabolism of isoflavones by gastrointestinal contents from rats and from humans (UK and Asian Populations).

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32. Private Communication

PUBLIC HEALTH LINK MESSAGE [UNITED KINGDOM] Released 18 July 1996

******EMBARGOED******

PLEASE CASCADE TO HEALTH PROFESSIONALS URGENTLY. THIS MESSAGE IS SENT TO YOU IN ADVANCE OF A PRESS BRIEFING AT 10.30AM ON THURSDAY 18 JULY 1996. PLEASE DO NOT DISCLOSE TO THE MEDIA IN ADVANCE OF THE PUBLIC ANNOUNCEMENT

To: All Directors of Public Health
Cc: Consultants in Communicable Disease Control
From: Sir Kenneth Calman, Chief Medical Officer, Department of Health

Date: 17th July 1996

Reference: CEM/CMO/96/8

Category: *URGENT MESSAGE-PLEASE ACTIVATE THE CASCADE*

PHYTOESTROGENS IN SOYA INFANT FORMULA MILK

Dear Colleague

Please forward the attached message urgently to the following Health Professionals to ensure that they have this information by 10.30am Thursday 18 July at the latest:

All General Practitioners and practice nurses

All community pharmacists via the procedure for Class 1 Drug Alerts

Medical Directors in all NHS hospital units to cascade to appropriate Health Professionals - in particular:

Paediatricians

Obstetricians

Dieticians

The Chief Executive of the Health Authority

Chief Executives on community health units

Thank you for your co-operation.

THIS MESSAGE IS TO BE CASCADED TO HEALTH PROFESSIONALS URGENTLY SO THAT THEY MAY BE PROPERLY INFORMED IN ADVANCE OF A PUBLIC ANNOUNCEMENT THE DEPARTMENT WILL BE ISSUING A PRESS NOTICE ON THURSDAY 18TH JULY (10.30AM).

IT IS IMPORTANT THAT THIS MESSAGE SHOULD NOT BE DISCLOSED UNTIL THAT TIME IN ORDER FOR IT TO GET TO RELEVANT HEALTH PROFESSIONALS FIRST

17 July 1996

CEM/CMO/96/8

MESSAGE FROM THE CHIEF MEDICAL OFFICER

Dear Colleague

*****SOYA-BASED INFANT FORMULA FEEDS*****

SUMMARY

The Department of Health will issue on Thursday 18th July a Press Notice concerning advice from the Committee on Toxicity (COT) about phytoestrogens in soya-based infant formulae.

Phytoestrogens are naturally-occurring chemicals which are present in the soya protein used in these formulae and which have weak oestrogenic activity. It is this aspect which has given rise to some concern. There is only limited information available on phytoestrogens and the expert committee's advice is that research is needed as a matter of high priority to determine whether ingestion of soya-based formulae by infants carries any risk for their subsequent reproductive development.

UNTIL THE RESULTS OF THIS RESEARCH ARE AVAILABLE THE DEPARTMENT'S ADVICE, WHICH HAS BEEN ENDORSED BY THE EXPERT COMMITTEE, IS THAT INFANTS WHO ARE BEING FED WITH A SOYA-BASED FORMULA ON THE RECOMMENDATION OF A DOCTOR OR OTHER HEALTH CARE PROFESSIONAL SHOULD CONTINUE TO RECEIVE IT.

A Patient Information Leaflet is attached which can be copied and given to parents enquiring about soya-based feeds.

BACKGROUND

The Department of Health's committee of independent experts, the Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment has recently reviewed the health aspects of phytoestrogens as part of an ongoing programme of reviews on naturally-occurring chemicals. It noted that some types of phytoestrogens have caused infertility in animals grazing on phytoestrogen-rich plants and adverse effects on sexual development in laboratory animal studies, although many of these findings followed exposure to coumestans, a different class of phytoestrogens from those found in soya. Two preliminary studies undertaken in a small number of premenopausal women in the UK have shown that modest

ingestion of soya protein (c. 60g per day) affected certain parameters of the menstrual cycle; mid-cycle peaks of LH and FSH were suppressed and the duration of the follicular phase was increased.

The COT has emphasised that it is not aware of any reports to suggest that populations which habitually ingest high quantities of soya, such as the Chinese or Japanese, have impaired fertility or altered sexual development. The COT has recommended that research should be undertaken as a matter of high priority to determine whether ingestion of soya-based formulae affects infant reproductive development in any way.

CURRENT ADVICE

While cows milk formulae are preferable for the majority of bottle-fed infants in the UK, soya-based formulae are given to about 2-4% of bottle-fed babies (approx 1% of all babies), usually because they are or may be intolerant of cows' milk protein. The COT has advised that where infants are being given soya-based formulae on the advice of a health care professional, THIS SHOULD CONTINUE. Soya-based formulae are of entirely plant origin and so are acceptable to vegans. The Department is advising vegans to continue to use soya-based formulae but they may wish to discuss the issue with health care professionals.

Other soya products are available for consumption by all age groups, including soya-based milks for toddlers, which are also useful for vegans and those intolerant to cows' milk. Parents should continue to give children these products. As part of a mixed diet, these products would not constitute the sole source of nutrition and therefore intakes of phytoestrogens are likely to be lower.

If you have any enquiries about this message please contact:-

either Dr Daphne Jaeger, Department of Health, Room 651C Skipton House, 80 London Road, London SE1 6LW. Tel: 0171-972-5311, Fax: 0171-972 5134

or Professor Martin Wiseman, Room 632B Skipton House.

Tel: 0171-972-5325.

PATIENT INFORMATION LEAFLET

****SOYA-BASED INFANT FORMULA FEEDS****

1. WHY ARE SOYA-BASED FORMULAE USED?

Breast feeding is the best way of feeding infants and can protect babies from developing allergies. Infant formulae provide an alternative source of nutrition when mothers cannot breast feed or choose not to do so. Cows' milk formulae are the preferred source of nutrition for the majority of bottle-fed infants. However, babies may be given soya-based formulae for one of the following reasons: (1) a small number of babies cannot tolerate cows' milk. (2) some parents choose for

themselves to feed their baby soya-based formulae because they have a family history of allergy or for other reasons; (3) soya-based formulae are made entirely from plants and this makes them acceptable to vegans and other groups who do not want to use feeds based on cows' milk.

2. SHOULD I STOP FEEDING MY BABY SOYA-BASED INFANT FORMULAE?

If your baby is under one year of age and your doctor has recommended that you feed your baby with a soya-based infant formula you should continue to do so. If your baby is over one year of age, you should ask your doctor or other health care professional about introducing your baby to cows' milk as babies can outgrow allergies.

3. WHAT SHOULD I DO IF I AM FEEDING MY BABY SOYA-BASED INFANT FORMULA BUT NOT ON THE ADVICE OF MY DOCTOR?

If you are using a soya-based formula but not on the advice of your doctor or another health care professional, talk to your doctor or other health care professional about whether to continue using it or whether to switch to another type of feed.

4. WHAT IF I HAVE ALREADY FED MY BABY SOYA-BASED FORMULAE?

At present, there is no evidence that phytoestrogens in soya-based formulae cause any problems. Research is being undertaken in the UK and internationally to give a better understanding of how phytoestrogens work in the body. If you are worried, you should discuss this issue with your doctor or other health professional.

5. IS THERE ANY ALTERNATIVE TO SOYA-BASED FORMULAE IF MY BABY CANNOT BE BREAST FED OR CANNOT BE FED COWS' MILK-BASED FORMULAE?

A more specialised feed is available, but it has to be prescribed. Discuss this with your doctor.

6. WHY ARE PEOPLE CONCERNED ABOUT SOYA-BASED INFANT FORMULAE?

For infants up to 4-6 months of age, soya-based formulae can be given as the only source of nutrition.

Phytoestrogens occur naturally in plants and the soya bean is a rich source of phytoestrogens. As a consequence, soya-based infant formulae also contain these substances. In certain situations these chemicals can behave like a very weak form of the female hormone oestrogen which has given rise to some concern. Work is underway which will give a better understanding of how the phytoestrogens in soya behave in humans since these actions are complex and not completely understood.

7. IS ONE BRAND OF SOYA FORMULA BETTER THAN ANOTHER?

There is only limited information worldwide on the levels of phytoestrogens in soya infant formulae and no information yet on the levels in the different brands available

in the UK. The Government has commissioned work to obtain this information but the results will not be available until next year.

8. WHAT ABOUT OTHER FOODS?

Other soya products are available for all age groups, including soya milks for toddlers. There is less concern about these products because as part of a mixed diet they would constitute a small proportion of the total food intake.

IMPORTANT NOTICE ABOUT BREAST FEEDING TO ACCOMPANY PATIENT INFORMATION LEAFLET

Breastfeeding is best for babies. It's natural, it's nutritious and it's free. Breast milk provides the nutrients essential for healthy development and contains antibodies to help your baby fight infections. It is easily digested and less likely to cause stomach upsets, diarrhoea or constipation. It's the only food naturally designed for your baby.

Begin breastfeeding straight away; otherwise it can be difficult to get started later on. Similarly, if you stop breastfeeding for any reason, it can be very difficult to re-start. Combination feeding (breast milk and formula) may also reduce the supply of your own breast milk. A good diet, some exercise, sufficient rest and support from those around you will help you to breastfeed successfully. Be sure to follow a healthy balanced diet when breastfeeding. And remember, this is the normal natural way of feeding your baby, so don't be embarrassed about it.

If you plan to use formula milk, take the cost and social implications into account first; and it is very important for your baby's health that you follow all preparation instructions carefully.

[End of patient information]

Statement by the [United Kingdom] Food Advisory Committee Released 18 July 1996

Phytoestrogens

We note that effects of phytoestrogens depend on the population concerned. There is some evidence to suggest that phytoestrogens may have beneficial effects in adults. However, there is a potential for these naturally occurring compounds to affect infants adversely. Therefore we fully endorse the need to undertake research at the earliest opportunity to establish a better scientific basis for characterising any risks to infants consuming soya-based infant formulae. We note that a number of topics that the COT has highlighted for study are already under investigation as part of MAFF's research on phytoestrogens. We wish to be informed of the outcome of this work at the earliest possible date.

Nevertheless we are reassured by the advice of the COT that parents who have been advised by their doctor or other health professional to feed their baby with soya-based infant formula should continue to do so.

However we consider it prudent for manufacturers of infant formulae to note the concerns of the COT and investigate means of reducing the levels of phytoestrogens in soya-based formulae as a precautionary measure. We note that some foods eaten by infants after weaning and by other population groups, including older children, contain soya and that we will need to consider whether any action is required in the light the outcome of the recommended research. We recommend that food manufacturers are made aware of this possibility and kept informed of any developments.

We note that surveillance data, and thus reliable estimates of phytoestrogen intakes from foods, is minimal and welcome MAFF's research and surveillance to address this question.

Statement by the NZ Ministry of Health

Released 19 July 1996

Soy Based Infant Formulas a Useful Alternative

Breast milk is best for infants. Dairy based substitute formulas can be used if needed however, and under the advice of a health specialist soy based infant formulas are a useful alternative for babies who cannot tolerate dairy based formulas, says Dr John Eastwood, Ministry of Health Paediatrician.

A recent statement from the Chief Medical Officer of the United Kingdom Department of Health that if your doctor or Health professional has recommended that you feed your baby soy based infant formula, you should continue to do so. This is in line with the advice that the Ministry has been providing in New Zealand since August 1995.

"The Ministry of Health has consistently advised people that breast feeding is the best way of feeding infants. Infant formulas provide an alternative source of nutrition when mothers cannot breast feed or choose not to do so.

"Cows' milk formulas are the preferred source of nutrition for the majority of bottle-fed infants however, some may have soy based formula if they cannot tolerate cows' milk or their parents are vegans," says Dr Eastwood.

"There is no evidence to date that these formulas are unsafe but concerns have been raised about the safety of certain natural components of the soy based formulas. Research is being undertaken into the effect of any of these compounds on infants but it will be some time before the results are known.

"The scientific evidence to date has focused on potential risk without adequately demonstrating that any adverse health effects are occurring, so we still have no reasons for changing our advice on the nutritional value of these products.

"Our current position is that the benefits of having available soy based infant formulas, as a useful alternative to breast feeding and dairy based formulas, outweighs any perceived risks.

"We appreciate the Chief Medical Officer's statement and the call by UK authorities for further research on this issue," says Dr Eastwood.

The Ministry contracted Dr Pat Tuohy, Policy Director, Royal New Zealand Plunket Society, to review the issues. The Ministry also contracted ESR to do a literature review. Its results show from the current evidence there are no adverse health effects from soy based infant formulas. The Ministry is currently looking at contracting ESR to do further work on phytoestrogens this year.

For more information contact:

Janet Lucas, Senior Communications Advisor, (04) 496 2067 or 025 477 036

Statement by the Soy Information Network

Released 19 July 1996

Soy Formula Risk?

The United Kingdom Department of Health yesterday recommended that research should be undertaken "as a matter of high priority" to determine whether soy based infant formulae create risks to the normal reproductive development of infants.

The recommendation follows reports of a Department of Health committee of experts on the effects of phytoestrogens on animals and humans. The report found that phytoestrogens, or plant oestrogens, were a cause of infertility in animals and influenced the menstrual cycle in women. It had also been shown to cause androgenisation of females and femininisation of males in certain species. Soy beans contain high levels of phytoestrogens.

The Committee said it did not have data "specifically relating to the potential effects of soy phytoestrogens in human infants" and recommended research on the issue "as a matter of high priority." The Committee went on to say that as a result of further research "it may be necessary to consider the potential risk of soy products to other sectors of the population."

The Committee has stopped short of recommending the removal of soy formulae from the market, but recommends that it should be used only when prescribed by a doctor or other health professional. Manufacturers of infant formulae have been urged to investigate means of reducing the levels of phytoestrogens in soy based formulae as a precautionary measure.

The findings of the Committee vindicate the work of a group of New Zealand researchers and others who have been challenging the safety of soy infant formulae for some time.

"While we continue to believe that soy infant formula should be removed from the market, we are pleased that the British Government has acknowledged that there are serious questions as to its safety. We would expect a similar response from the New Zealand Ministry of Health," said Dr David Woodhams, spokesperson for the Soy Information Network.

Readers are invited to compare the following press coverage with the source documents.

"'No need' for baby food panic" Reprinted from the "Guardian", London 18.7.96

Fresh fears emerged yesterday over the safety of baby food as the Government said manufacturers of soya feeds should look at the ways of reducing oestrogen-type chemicals in such products. The chemicals, called phytoestrogens, occur naturally in soya but there are some concerns that these might affect fertility.

The Committee on Toxicity of Chemicals in Foods, Consumer Products and the Environment, made up of independent experts, has advised that phytoestrogens can, in certain situations, behave like a very weak form of the female hormone oestrogen. In animals it had caused some fertility problems.

However, the Department of Health said parents who had been advised on medical grounds to give their baby soya based formula should continue to do so. There was no evidence of adverse effects in populations which ate large quantities of soya such as the Japanese and Chinese. By C. Mihill

"Mothers urged to seek advice over babies' soya milk."

reprinted from the "Daily Telegraph", London, 19.7.96

Mothers who feed their babies on soya milk formulae in preference to those made from cows' milk should seek their doctor's advice on whether to continue doing so, the Department of Health said yesterday.

It follows research showing that naturally occurring chemicals similar to those contained in soya can cause infertility and sexual abnormalities in animals.

The Department stresses that there was no evidence suggesting a similar effect to humans and it was not recommending that mothers should stop feeding soya-based milk to their babies.

But it announced that it was giving "high priority" to research investigating whether soya milk formulae carry a risk to the future development of babies' reproductive organs.

Sir Kenneth Calman, the Chief Medical Officer, said, "Mothers who have been advised on medical grounds to give their baby soya based formula should continue to do so."

However, parents who had chosen soya milk in preference to cows' milk - such as vegans and those opposed to eating animal products - should seek their doctor's advice, he added.

He activated the Department's "urgent cascade system" to send out more than 60,000 letters to alert all general practitioners, practice nurses and community pharmacists to the warning.

Concern centres over naturally-occurring chemicals present in soya called phytoestrogens.

Some types of phytoestrogens in clover are known to cause infertility and aggression in sheep in a condition named Clover Disease. Laboratory studies have also shown that phytoestrogens can affect animals' sexual development.

Phytoestrogens act like a weak form of the female hormone oestrogen and eating regular amounts of soya protein has been found to affect women's menstrual cycle.

But the Government's Committee on Toxicity said it was not aware of any evidence that Chinese or Japanese people, who have a high level of soya in their diet, were affected by phytoestrogens.

Prof Frank Woods, chairman of the committee, said: "We could find no evidence of an increased incidence of the sort of abnormalities you might expect in the development of the female or the male genital tract in these populations.

The government has commissioned research to find out whether levels of phytoestrogens vary in different brands of soya milk but it said the answers would not be available until next year.

It has also asked food manufacturers to look at ways of reducing phytoestrogen levels in their product.

The Infant and Dietetic Foods Association said last night that soya milk formulae had been used for up to 40 years without any evidence of being harmful to babies.

"Parents should not be persuaded to switch from their soya formula to another formula which may not be suitable for their child," it said.

Phytoestrogens were a natural part of soya and were present in garlic, cabbage and apples. They could be present in breast milk depending on the mother's diet. About 6,500 babies are fed on soya formulae - one percent of babies born each year.

The Department of Health's concern follows the disclosure last May that a related type of chemical, man-made phthalates, were present in some brands of baby milk formula and could be responsible for falling sperm counts in men.

By David Fletcher, Health Correspondent

"Parents warned of risks from soya milk"

reprinted from "The Times", London, 19.7.96

Parents who chose to give their babies soya-based infant formula milk should seek medical advice about the risks, the Government said yesterday.

A committee of independent scientists appointed by the Health department has said that phytoestrogens found in soya-based infant formulae can sometimes behave like a very weak form of oestrogen, the female hormone. In animals this has caused fertility problems. The Committee on Toxicity of Chemicals in Foods, Consumer Products and the Environment says there is no evidence of damaging effects in humans.

About 1 per cent of babies are fed soya-based milk, most on medical advice because they are allergic to cows' milk. The committee says these children should continue to be given soya-based milk.

Last month the Food Advisory Committee recommended that, as a precaution, baby-food manufacturers should look at how to reduce phytoestrogen levels in their products.

The concern over phytoestrogens is separate from that relating to another oestrogen-like chemical found in some baby milk in the form of phthalates, which have also been linked to infertility.

By Jeremy Laurance

“OUR STOLEN FUTURE”

Theo Colburn

The following is a quotation from p 171 of the recent book “Our Stolen Future” by Theo Colburn and others. The author's concern is with substances in the environment and in food that mimic estrogens.

“A number of paediatricians from various parts of the U.S. have expressed their concern about an increasing frequency of genital abnormalities in children such as undescended testicles, extremely small penises and hypospadias, a defect in which the urethra that carries urine does not extend to the end of the penis, but it is virtually impossible to document these anecdotal reports. Unfortunately, the problems caused by endocrine disruption may have to reach crisis proportions before we have a clear sign that something serious is happening.”

“THERE ARE NO REPUTABLE STUDIES....”

Dave Woodhams

“The Ministry of Health and the Plunket Society moved to allay fears that soy-based milk formulas could be harmful to babies. Both said they were unaware of any reputable studies showing soy-based milk products could have adverse health effects.” (NZPA 9 Dec 94)

In the course of the last one and a half years almost every commentary on the concerns raised in the Fitzpatrick Report has echoed these statements. Nestlé's, for instance, stated to the World Health Organisation and thence to the Ministry of Health (14.12.94) that “...there is no epidemiological or clinical evidence to suggest that consumption of soy-based infant formulas produces an endocrinological risk to infants.” This is repeated in essence four times in a four page statement. See also the COT Statement.

There are, in fact, numbers of reputable studies showing adverse health effects from soy infant formula. References to some of these studies were in the Fitzpatrick Report. However, some of them were allergic reactions, which don't count. Others have been called 'idiosyncratic' effects, which means that they are said to be due to a peculiar susceptibility of the individual affected. Apparently these don't count either.

Recently, however, Mike Fitzpatrick found a paper¹ that had previously escaped our attention. Published in 1990 by a team from the Dept of Pediatrics, North Shore University Hospital, Cornell University Medical College, it describes an epidemiological investigation of 59 children with autoimmune thyroid disease, their 76 healthy sisters and brothers and 54

healthy unrelated control children. The team was interested in any association between soy formula feeding in infancy and the later development of autoimmune diseases of the thyroid.

A detailed history of feeding practices for the children revealed that there was no difference in the frequency and duration of breast feeding in early life among the three groups of children. However, the frequency of feedings with soy-based milk formulas in early life was significantly higher in children with thyroid disease (31% of this group) as compared with their siblings (12%) and the healthy unrelated control children (13%). The probabilities of these results arising by chance are less than 1% for the sibling comparison and less than 2% for the control group. As the authors state in their summary of the work: **“Therefore, this retrospective analysis documents the association of soy formula feedings in infancy and autoimmune thyroid disease.”**

We have consistently argued for this sort of epidemiology to be done for a number of possible soy isoflavone effects on the developing infant. At least now there is no excuse for claiming that there are no reputable studies showing adverse effects.

1. Fort, P., Moses, N., Fasano, M., Goldberg, T. and Lifshitz, F. “Breast and soy-formula feedings in early infancy and the prevalence of autoimmune thyroid disease in children.” *Journal of the American College of Nutrition*. 9(2):164-7, 1990 Apr.

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Press cuttings of NZ articles covering the release of the COT statement from the NZ Herald (First Edition, 19.7.96), the Dominion (22.7.96), the Evening Post (22.7.96), the Northern Advocate (19.7.96) and Healthy Options (by permission of the Editor) are attached.