

## **Toxic Love: Soy Baby Formula, Healthy Alternative or Unnecessary Harm?**

Babies all over the world who are being fed soy-based infant formula are taking a part in a huge experiment with the potential for highly dangerous outcomes, according to many scientists.

Former director of the Food and Drug Administration's Centre for Toxicological Research Dr Daniel Sheehan called feeding soy formula "a large, uncontrolled and basically unmonitored human infant experiment".

Scientific evidence is growing that parents who buy the formula to feed their babies each day might unknowingly be preparing a potentially toxic concoction which could irreversibly damage the long-term health of their children.

New Zealand toxicologist Dr Mike Fitzpatrick says parents have the right to know that soy-based formula contains potentially harmful compounds.

Many other internationally renowned scientists have joined Dr Fitzpatrick, one of the first to sound the alarm, and expressed their growing concern about the potential for health complications that could result from giving phytoestrogen-rich soy formula to babies.

Phytoestrogens are plant-derived compounds that have the ability to mimic the actions of the female hormone oestrogen.

The group of phytoestrogens in question called isoflavones, are genistein and genistin, and their oestrogen mimicking behaviour has been the subject of many international studies.

In a 2010 study, scientists from the University of Illinois, working in conjunction with the US Food and Drug Administration's Division of Biochemical Toxicology

(FDA) and the Department of Food Science and Human Nutrition (DFSHN) estimated that an infant consuming soy formula receives several hundred times higher amounts of this plant-based oestrogens than adults consuming normal Western diets.

This high exposure to phytoestrogens occurs during a stage of life when it could cause reproductive and other effects during neonatal and/or adult life, the study says.

Dr Fitzpatrick estimates that infants who are exclusively fed soy formula consume the equivalent of five birth control pills worth of oestrogens on a daily basis.

“My feeling was that any foreign hormone or any foreign substance in a human being is bad, in a baby it’s really bad,” he says.

New Zealand food scientist Dr David Woodhams took the nutritional information on soy formula labels and calculated what the daily dose per kg per body weight would be if a mother followed the direction on the box.

The results were alarming.

“The estimate that I made was that babies were getting three to five times the dose that has been demonstrated to have physiological effects in pre-menstrual women,” says Dr Woodhams.

A 1994 study, *Biological Effects of a Diet of Soy Protein Rich in Isoflavones on the Menstrual Cycle of Premenopausal Women*, showed phytoestrogen doses approximately 10 times fewer than what babies are exposed to on a daily basis disturbed the menstrual cycle of women.

And there are other concerns. Separate studies have also linked soy formula to the development of abnormal thyroid function, possible toxicity and infertility later in life.

Dr Retha Newbold, a staff scientist and developmental biologist in the Toxicology Branch at the National Institute of Environmental Health Sciences (NIEHS) in North Carolina, has studied the effect of isoflavones in prenatal and neonatal exposure in mice.

“What happens early on is you see changes in the ovaries, changes in the oviduct and if we wait long term and look at the animals after they grow up, say around 18 months of age, those animals have an increased incidence of uterine cancer.

“These problems we are finding at the same level that human babies are exposed to. It’s not higher doses that are toxic to start with, they are actually the same doses human babies are exposed to,” says Dr Newbold.

Like Dr Newbold, American nutritionist Dr Kaayla Daniel is also concerned with what these compounds could do to a developing child.

She says babies are the most at risk because their bodies and brains are still developing and the “wait and see” approach could be a “terrible mistake”.

She says there are some concerns for the general population.

“The most at risk would be babies on soy formula, and the reason for that would be that they are very small size, they are in the key developmental stages and they are not getting anything else to eat.

“For adults, for example, they might be eating a lot of it but presumably they would be eating a lot of other things too.

“The same with children. They would be eating a lot of other things too, but they are still developing, so a child that is eating a lot of veggie burgers and drinking soy milk is going to be more at risk than an adult who has presumably stopped growing.”

Dr Daniel says the soy industry is very powerful.

Soy is a big business.

In a 2011 worldwide study, Global Industry Analysts forecast that the global market for soy foods would reach US\$42.3 billion by the year 2015.

The US is the biggest exporter of soy and its soybean industry recorded exports worth US\$21 billion in the 2009-10 financial year, according to the American Soybean Association's website.

US-based soy grower Archer Daniels Midland (ADM) alone operates more than 240 processing plants and 330 crop-sourcing facilities in more than 60 countries on six continents.

The company recorded net sales of US\$62 billion in the financial year ended June 30, 2010 and is also featured in the *Fortune 500* list at number 39, right after Microsoft.

In 2009, soybeans accounted for 53 per cent of world oilseed production, and 38 per cent of these soybeans were produced in the US.

Part of this massive production is turned into soy baby formula. Euromonitor International estimates that New Zealand parents bought close to NZ\$2 million worth of soy formula in 2010. That is compared with US\$600 million in the US and close to ¥800 million in Japan.

Soy products are found throughout Asia, but scientists and historians stress that the first to use soy formula were Westerners.

They say the myth that soy formula has been around for centuries in places in Asia and thereby can be considered safe has no basis in reality.

Dr Daniel says soy formula was invented by a paediatrician in Baltimore, US in 1909.

“Soy formula was first used in Asia when Seventh Day Adventist missionaries from the US started popularising it.”

She says babies that were not breastfed either went to a wet-nurse or they were given something like buffalo milk, mare’s milk or they just died.

“So, soy milk seemed to be a wonderful solution and they (the missionaries) had the very best intention but the point that soy formula was used in Asia for many, many years is just not true,” says Dr Daniel.

The first documented use of soy formula in China was published in the *Chinese Journal of Physiology* in 1928.

Dr Ernest Tso, Professor of Paediatrics of the former Peking Medical College wrote: “Soybean milk is a native food but it is little used as part of the diet for children.”

Dr Fitzpatrick notes that although soy has been a wider part of the traditional adult Asian diet for centuries, there the use of soy was different in two ways.

“Number one; they didn’t eat a lot. Number two; their soy products were manufactured completely differently. They would treat it for years; sometimes they would ferment it for three years, which broke down a lot of the toxins, including oestrogens.”

Dr Fitzpatrick says the way the Western soy industry makes soy products in its factories is completely different.

“They get the soybean and they squash it and the milk comes out of it, then they separate the oil from the milk and what they do then is extract the protein from the milky stuff and then dry it, and end up with this white powder.

“And then they take this white powder and stick it in food and they do this in a day or two, so, they don’t give it the attention that the Asian people did when they were making it. It is all very fast, very quick and a completely different form, a completely different type of soy. It is called isolate soy protein.”

The toxicologist says Asian people did not eat isolate soy protein, which is what is in baby soy formula and other modern soy foods, but used bean curd to make different types of food.

“In the West there is that mass production of isolate soy that is quite different and because of that it contains the oestrogens in much higher levels than the Asians were exposed to.”

But that same isolate protein is used in soy baby formula and has created growing concerns and calls for governments to do more to protect babies, or at the very least educate mothers better about the possible dangers and the safer alternatives, which exist.

Scientists interviewed stress that although some governments and regulatory bodies around the world have taken steps to protect babies by issuing warnings and demanding restrictions, it appears that not much of that information has reached parents.

On the UK’s Department of Health website a warning issued by the former chief medical officer, Sir Liam Donaldson, says: “Soy-based infant formulas have a phytoestrogenic content, which could pose a risk to the long-term reproductive health of infants, according to a 2003 report from the Committee on Toxicology (COT), and an independent scientific committee that advises the Department of Health and other agencies.

“The Scientific Advisory Committee on Nutrition (SACN), another independent advisory body, has advised that there is no particular health benefit associated with the consumption of soy-based infant formula by infants who are healthy (no clinically diagnosed conditions). SACN also advised that there is no unique clinical condition that particularly requires the use of soy-based infant formulas.”

Dr Donaldson advised that soy-based infant formula should not be used as the first choice even in cases when medically indicated such as for the management of infants with proven cow’s milk sensitivity, lactose intolerance, galactokinase deficiency or galactosaemia.

“As an alternative to soy-based products, the more appropriate hydrogenised protein formulas are available and can be prescribed.”

Hydrogenised or elemental baby formula is where the protein has been broken down to smaller particles, essentially into amino-acids, making it suitable for infants and children with cow’s milk allergy, multiple food protein intolerance, and a range of other food allergies.

The Canadian Ministry of Health also recommends the use of hydrogenised infant formula for treatment in cases of proven cow’s milk allergy and identifies the use of soy-based infant formula in these cases as “controversial” and “inappropriate”.

The Israel Health Ministry in 2005 issued a warning recommending soy formula should not be given to infants at all.

The French authorities have also issued strong warnings.

The French Food Agency (AFSSA) published a report in 2005 which recommended that soy should not be given to children under three years of age. It also called for better labeling and the removal of phytoestrogens from soy-formula.

In a press release the AFSSA said the consumption of phytoestrogens “cannot *a priori* be considered safe, because they interfere with the hormonal system, and as such merit examination”.

In 2007, warnings for parents, medical practitioners and the general population were issued by The Federal Institute for Risk Assessment in Berlin, Germany. The institute said that the isoflavones found in soy could pose health risks and babies should not be given soy infant formula without apparent, unavoidable medical reasons and then only under rigorous medical supervision.

New Zealand’s Ministry of Health (MoH) was one of the first countries to issue a statement on its website in 1998 but it is qualified, cautious and generally weaker in tone than those just mentioned.

“Over the past decade there has been some concern among health practitioners and policy makers about the safety of soy-based infant formula, mainly about the high level of phytoestrogens in soy-based infant formula,” the ministry warns.

The statement identifies phytoestrogens’ female hormone-like behavior and adds: “The long-term effects of phytoestrogens on an infant’s development are not known, although as yet there is no conclusive evidence of harm. However, international research has indicated that phytoestrogens can cause changes to sexual development in animals. The research suggests that, in rare circumstances, the phytoestrogens in soy-based infant formula may affect the function of the thyroid gland.”

In sharp contrast to the UK’s recommendation, however, the New Zealand Ministry of Health suggests that soy-based formula should be used where medically indicated.

Many of the scientists we spoke to, however, are concerned that all of that information and all of those warnings are not reaching parents, and many parents

around the world use soy formula because they think it is the better and even healthier alternative to cow's milk formula.

The disputed benefits of soy had some media coverage in New Zealand in the past but nothing since 2007.

Consequently the issue gets little political attention.

One lone voice trying to remedy this is former Green Party MP Sue Kedgley.

She says there should be warning labels on soy baby formula.

The main issue is that the New Zealand labeling laws are decided in Australia by Food Standards Australia New Zealand, where New Zealand has one vote out of 11.

"They don't act on most issues and don't seem to take the Precautionary Approach," she says.

The Precautionary Principle or Precautionary Approach in science advises that the public should be protected from exposure to harm in cases where scientific investigations have found a plausible cause for concern.

It proposes that when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof.

Concerned scientists agree and strongly urge the Precautionary Approach should be applied to soy-based infant formula.

US developmental biologist Dr Newbold says she cannot think of another population that needs the Precautionary Principle applied more than infants and children.

Dr Fitzpatrick, like many other international scientists, agrees.

“If you don’t know the answer [to phytoestrogen safety] don’t expose children.”

Miss Kedgley says just having a statement on the New Zealand Ministry of Health’s website is not enough to inform parents of the potential dangers.

“All the New Zealand Ministry of Health is doing by having it on their website is covering their tracks.

“There should be proper warning on packs,” she says.

In fact, a 2007 Health Select Committee, of which the New Zealand MP was a member, recommended stronger warning labels on soy infant formula and more parental education about the risks of feeding infants soy-based formulas.

That recommendation was ignored.

“I am astonished that the Australian New Zealand Food Authority (ANZFA) is going against a Ministry of Health submission that parents should be told not to use soy infant formula except on advice of a health professional,” says Ms Kedgley.

“It is incredible that ANZFA has brushed off expert advice from the ministry and decided to allow soy formula to remain on sale without any cautionary labels at all.”

The New Zealand Government’s official response to the Health Committee’s proposal published on the New Zealand Parliament’s website says it intends to take action on the committee’s recommendation for more proactive education on soy-based infant formula, but is unable to respond positively to the recommendation of additional mandatory labeling because it considers there is insufficient evidence of any potential harm to warrant such additional labeling.

So much for the Precautionary Principle.

While ignoring the call for better labeling the Government did however agree to provide better education for parents and to discuss voluntary labeling with the soy manufacturers, but it is more than a little vague now on what has been achieved since then.

In a written response to our question asking what specific actions it has taken, the Ministry of Health responded that information about soy-based infant formulas has been included in “relevant Ministry publications” such as, the Wellchild book and the *Food and nutrition guidelines for infants and toddlers* (aged 0-2).

“Information about soy-based infant formula has been provided to media and published where appropriate.

“Voluntary labeling of phytoestrogens content on infant formula products has been discussed with industry. Those discussions resulted in the proposal not progressing.”

No surprise there, industry is unlikely to want off-putting warning labels on its products.

One of New Zealand’s main providers of education for new parents is Plunket. We asked what advice, if any, the organisation gives in relation to feeding baby formulas in general and soy formula in particular.

Avoiding the issue as best it could, the organisation that many mothers turn to first seems to have no policy on soy formula.

In a statement Plunket said: “The Ministry of Health has overall responsibility for the management and development of the New Zealand health system and provides leadership across the system. This includes the development of policy, legislation and clinical guidelines.

“Plunket is New Zealand’s largest provider of services to support the health and development of children under five. Any advice Plunket gives is based on healthy policy, legislation and clinical guidelines provided by the Ministry of Health.”

Plunket’s attitude highlights the concerns of those who say that while frontline organisations like Plunket place the responsibility with Government ministries, little action is taken and even then this is often confined to warnings on relatively obscure and little consulted websites.

Dr Woodhams says he is not surprised the New Zealand Government rejected the submission made by the 2007 Health Committee, but is surprised the committee made it in first place.

“I was then in a fight for years with the Ministry of Health just to get them to admit that there was a problem.”

Former *New Zealand Herald* and *North&South* writer Camille Guy, who did some early stories on problems associated with soy, says the Ministry of Health was “very resistant” to change when it came to soy formula regulations.

“I think we have been lobbied by the American soy industry and food industry to preserve the status quo.”

Scientists say that as a result of that powerful lobbying, mothers around the world remain oblivious to the fact that soy formula could have devastating effects on their growing child and that what little parent information that is provided by health authorities is often ambiguous and inconclusive.

Dr Woodhams says he’s been fighting for years to make incremental gains.

“I don’t think that governments are reacting appropriately and I think that in part that is because of the huge power of the soy industry.”

Dr Kaayla Daniel agrees. “The only governments that are doing something would be Israel, France and Germany. They have basically issued warnings to parents and pediatricians. In many countries like the US many pediatricians have never heard that there is a problem or parents don’t know. They have heard that soy is a healthy food, so they just assume that it is good for the babies.”

Despite all the growing evidence, and the fact the 2007 Health Committee recommended better labeling and education in New Zealand, it has been one of the countries that has reacted relatively slowly to perceived dangers.

The official at the New Zealand Ministry of Health responsible for babies and young children, child and youth chief advisor Dr Pat Tuohy, who is also the author of the ministry’s statement on soy formula, says he is aware of the other countries’ warnings but does not think there are significant problems from using soy-based formula for most babies.

“The evidence that I have seen, apart from the potential risks to thyroid function, almost none of the other articles published in the last three or four years, have come out with any strong evidence that there are significant bad outcomes for babies.”

Dr Tuohy, however, thinks that even so, the Precautionary Principle should be applied and that was what he proposed in 2007.

“We should only use soy infant formula when a doctor believes that the benefits of using it are likely to outweigh any potential harm from it.

“I have to say in taking the view, which I have taken, which is suggesting that the Precautionary Principle be applied, has not been fully agreed with by my colleagues in paediatrics.”

Dr Ralph Wiles, from the Royal New Zealand College of General Practitioners, says he discusses with parents the potential problems associated with the phytoestrogens in soy formula.

“It has not been a problem recently because we haven’t used it but of course they can go and use it without me knowing because they can buy it over the counter in the supermarkets.”

Dr Jan Sinclair, chair of the Allergy Interest Group of the New Zealand Paediatric Society says: “I think we have options in New Zealand for very young infants, so we may not use soy in very young infants.”

However, Dr Sinclair believes there is no data to say soy is harmful.

“I can refer you to the American Academy of Pediatrics statement, which says that soy is not promoted as better than anything else, but the long term studies have shown theoretic concern, but there is nothing that has been proven.

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“This is all very theoretical and I don’t think that people really know.”

She says it is not very helpful to make parents who cannot use cow’s milk feel guilty about using an alternative.

To anti soy formula campaigners that is simply splitting hairs and the lack of a smoking gun does not undermine the increasing body of evidence.

Dr Newbold, who has studied the effects of phytoestrogens for more than 10 years, says her studies found an increase in the incidence of uterine cancer and other problems with the reproductive tract, which could potentially lead to infertility.

“The studies are pretty clear and they are published in peer reviewed journals.”

In the last few years US scientists have been involved in the most comprehensive, multigenerational and lifetime exposure to isoflavones studies done to date.

A study conducted by the Division of Biochemical Toxicology (DBT), National Center for Toxicology (NCT) of the US Food and Drug Administration (FDA) suggests that it is now, “possible to predict internal exposures of children to genistein from soy infant formula,” and says the possible negative effects should be considered.

Another 2009 study, conducted by the US National Institute of Health in conjunction with the FDA’s NCT, says exposure to environmental oestrogens during critical developmental windows “has well-documented adverse consequences on males and females of many species, including rodents and humans”.

It also found that oral phytoestrogens altered ovarian function, delayed vaginal opening, caused abnormal oestrous cycles, decreased fertility, and delayed labour.

The US Food and Drug Administration’s Division of Biochemical Toxicology and the University of Illinois developed a study model in which mice were exposed orally to the same amount of the oestrogen-like compounds that infants fed soy formula would be exposed to.

The study found that these oestrogens affected the reproductive and immune systems of the neonatal mice.

Dr Newbold, who is currently conducting a study for the National Institute of Environmental Health Sciences in the US on obesity, says her research has found a possible link between soy phytoestrogens and obesity.

“This is something that is still being worked over but often times what you find is babies are given soy formula, and soy formula makes them gain weight, makes them gain more weight than breast milk would and we know from other experiments that if there is an excessive weight gain during neonatal life, those people have more tendency to be overweight as they age.

“This also ties to increased number of diabetics, metabolic syndromes and cardiovascular disease,” she says.

Sally Fallon, director of the Western A Price Foundation, a non-profit organisation dedicated to “restoring nutrient-dense foods to the human diet through education, research and activism,” says the US Food and Drug Administration has approved a health labeling of soy as beneficial for the heart but declined application for GRAS status.

GRAS status defines foods as **Generally Recognised As Safe**.

The FDA website explains: “Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.”

In 1998 some of the FDA’s own scientists such as Dr Daniel Sheehan, former director of the Oestrogen Based Program, and research chemist Dr Daniel Doerge wrote a letter opposing GRAS status for soy isoflavones.

“We oppose GRAS status because there is abundant evidence that some of the isoflavones, including genistein and equol, are toxicants. This is true in a number of species including humans.”

In 1999 they also opposed the “Food Labeling Health Claim of Soy” because of the potential for health complication if consumed by pregnant women or a young child.

Early development is recognised as the most sensitive life stage for oestrogen toxicity because of the indisputable evidence of a very wide variety of malformation and serious functional defects in experimental animals and humans, the scientists wrote.

US author and nutritionist Dr Daniel agrees that the FDA’s approval of the health claim for soy’s benefits for the heart may be misleading.

“It has helped give the impression that soy is a healthy substance and most people believe that. They don’t know much, they just assume that soy is healthy.

“Some people just assume that. It’s just this assumption that there are problems with dairy and that soy is good, so this is part of the problem.

“The FDA scientists were very clear about the problems and about the risk but in another part of the FDA, the Consumer Protection part, which is the part that most people are aware of, they had a completely different agenda.

“They were not listening to their own scientists.

“The FDA has approved drugs that are dangerous because of the pharmaceutical industry. Soy is big business.

“The FDA has approved things like aspartame; it has approved dangerous drugs; it approved soy.

“I think that if people think the FDA is looking after consumers they are very mistaken,” Dr Daniel warns.

Sally Fallon agrees.

“There is no leadership there to protect the public,” she says.

In 2009 a group of nine FDA scientists sent a letter to Barack Obama’s transition team begging him to restructure the agency, saying managers had “intimidated, instructed and coerced scientists to manipulate data in violation of the law”.

“There is an atmosphere at the FDA in which the honest employee fears the dishonest employee,” the scientists said.

They described the FDA as a “fundamentally broken” agency.

In 2009 the *Wall Street Journal* reported that the agency had come under pressure from the Houses of Congress for being too close too industry.

A number of US politicians, among them Senator Chuck Grassley, expressed concern that FDA leaders “often ignore or suppress their own scientists’ opinions on safety issues involving drugs and devices”.

Dr Daniel says the FDA has some of the very best laboratories in the world and the scientists there are very clear about the problems and risks associated with soy-based formula.

But those risks are not being passed on to the US public. Dr Newbold says soy formula is “really pushed” in the US.

“It is just widely available anywhere in the US and if a baby has a little upset stomach the parents often times just switch to soy formula.

“They come home from hospital with free soy formula. It’s really pushed.”

She doesn't think there is enough information for parents to allow them to make an informed decision.

The developmental biologist says that she doesn't even think here is enough information for paediatricians.

"It's hard to get the message across. The soy companies don't want you to get your message across."

Although Dr Newbold is still working for the US Government's National Institute of Environmental Sciences, Toxicology Branch her studies into the effects of phytoestrogens in neonatal life were shut down unexpectedly by the Government, which dispersed her staff without giving her any explanation.

"That was really all politics and I really was never given a reason, except that this is not the direction they wanted the research to go," she says.

Although she has no direct proof, Dr Newbold thinks that her anti soy findings may have influenced the Government's actions.

Sally Fallon says the US is where most of the world's soybeans are grown and the industry is extremely powerful there.

"We have done the best that we can to spread the word out there and it has been somewhat effective, but soy has been given in the Women, Infants and Children Programs.

"So soy formula has been foisted on Hispanics and Blacks, people who are poor.

"They want to give our precious babies the cheapest thing that they can make, that's why they like soy because it is extremely cheap."

Dr Mike Fitzpatrick was also involved in trying to get better labeling for US

mothers who might be thinking about using soy formula.

“One of the things we tried to do was to try and talk to people in California because there they have quite a different legal system to the rest of the states. They have The Right to Know Legislation.

“We were saying that mothers and fathers have the right to know that the soy formula contains these isoflavones.”

The response he says he got from the Californian Department of Health was that it did not agree that parents had the right to know that soy-based formula contained isoflavones and the kinds of toxicities isoflavones might demonstrate in infants, since “parents would not know how to interpret information that soy-based formulas contain isoflavones”.

Dr Fitzpatrick’s US colleague, Dr Newbold, says regulatory bodies may have heavy workloads, but perhaps they should prioritise better.

“I guess they have a lot of other things they are worried about and any time you talk to some of the regulators they say, ‘We have been using it for years, so, there shouldn’t be a problem’.

“That to me is not an answer. That just means that kids have been exposed for years.

“If you don’t look for a problem then you are not going to find it. If you are just sort of blind to a problem you are not going to find it.

“I understand they have a lot of regulations that they have to go through, but to me, none of that should be as important as children’s health.”

Dr Fitzpatrick says the soy industry has maintained in the past that it is not possible to remove phytoestrogens from soy formula because it would affect protein quality,

but says he was told by one of the industry's own scientists, Dr Mark Messina, that they can, but they won't do it because it is "too hard and too expensive".

Soy formula manufacturers contacted did not answer questions enquiring whether or not they could or would consider removing the phytoestrogens, or if they would consider voluntarily putting warning labels on soy formula packaging.

The manufacturers of soy formula sold within New Zealand, Wyeth and Nutricia, redirected questions to their mother companies the large multinational corporations Pfizer and Danone.

Questions were directed to Pfizer's head office in New York but answers had not been provided by the time of publication of this article.

Multiple unsuccessful attempts were made to establish contact with Danone's head office in France.

When first contacted the Infant Nutrition Council (INC), based in Australia, which represents formula manufacturers Wyeth, Nutricia and Nestle, said it would develop a position statement about soy-based infant formulas, signed off by the members.

The council's website identifies it as an "amalgamation of the Infant Formula Manufacturers' Association of Australia and the New Zealand Infant Formula Marketers' Association", representing the "significant majority" of companies marketing and manufacturing infant formula in Australia and New Zealand.

"The members of the Infant Nutrition Council work with key stakeholders to support the public health goals of promoting breastfeeding and good nutrition for infants," says the website.

The council has not yet provided the promised position statement and when contacted directly CEO Jan Carey would only say the "council supports the

assessment of Food Standards Australia New Zealand (FSANZ) and the American Academy of Pediatrics that there is no evidence that exposure of healthy infants to soy-based infant formula has been associated with any demonstrated harm”.

The council was approached again to respond to the specific claim that stricter labeling of soy formula has been resisted by the soy industry.

Carey responded.

“Soy-based infant formulas produced by INC members in Australia and New Zealand are recommended to be used following advice from a healthcare professional. They are formulated and labeled in compliance with the Australia and New Zealand Food Standards Code, and are considered safe and suitable nutrition for infants when used as recommended.

“Food Standards Australia New Zealand (formerly the Australia New Zealand Food Authority) has previously completed an assessment of the risks to infants from soy-based infant formula, and concluded that there is no evidence that exposure of healthy infants to soy-based infant formula has been associated with any demonstrated harm.

“A more recent review was published by the American Academy of Pediatrics, which we believe is consistent with the earlier FSANZ assessment.

“I hope this makes industry’s position clear (sic) which is based on scientific evidence.”

The council was also given the opportunity to comment on criticisms by scientists suggesting that soy formula labeling policy is shaped to suit manufacturers and their own interests, undermining what is best for babies’ health.

Carey responded by saying that all soy formula sold in New Zealand and Australia is safe because it follows very rigorous standards.

“I think as far as the industry is concerned we follow the Food Standards Australia New Zealand code and the research it has done shows that soy formula is safe for infants.

“So what I would say is that soy formula in Australia and New Zealand that is manufactured here in accordance with the food regulations and the food standards is safe for infants.”

FSANZ says an assessment of the risks to infants from the phytoestrogen content of soy formulas was undertaken by FSANZ in 2002 as part of its review of infant formula products.

“The information available at the time suggested that, while phytoestrogens have the potential to cause adverse effects, there was no evidence that exposure of healthy infants to soy-based formula over some 30 years of use was associated with any demonstrated harm.

“However, as there were no long-term studies of a high scientific quality looking at the effects of soy-based infant formula, it was recommended that they be used only on the advice of a health professional and for infants who have a special medical requirement that precludes breast feeding or modified cow’s milk formulas,” said the organisation in a statement.

The standards agency says it does not take a position on the use of soy formula pointing to the guidelines provided by the Australia New Zealand Food Regulation Ministerial Council, which it says had only been recently updated.

The new guidelines do not go as far as to require the labeling of phytoestrogens by soy formula manufacturers but interestingly say that in cases where a formula is designed to be suitable for infants with specific medical conditions the label should spell out that it should not be used in any other circumstances, or by healthy infants.

“Where a label contains a claim that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then the label on the package of infant formula product must include a statement indicating –(a) that the product is not suitable for general use and should be used under medical supervision; and (b) the condition, disease or disorder for which the food has been specially formulated; and(c) the nutritional modifications, if any, which have been made to the infant formula product.”

Which begs the question, if specialist soy baby formulas must not be fed to healthy infants why not label all soy formula the same way?

The FSANZ answer to this question dodges it rather. It says this is a small group of children with special and specific needs often under the supervision of a medical specialist. “Principles are designed to ensure these products for special dietary uses are safe, meet the nutritional requirement of the target group, their composition is evidence-based and they are appropriately labeled for their intended purpose”.

Many of the doctors and scientists we spoke to for this article would like to see similar labeling on all soy formula for the wider infant population, ensuring the composition of all soy formulas is “evidence-based and they are appropriately labeled for their purpose”. That way they say mothers could make an informed choice.

The FSANZ responded to the suggestion that it was “dragging its feet” by not applying the Precautionary Principle in relation to warnings on soy infant formula by saying it is preparing to review and potentially revise the policy guidelines on infant formula.

“This process will provide an opportunity to consider all relevant issues and concerns including current government and other authoritative recommendations as well as any new evidence about the health effects of consumption of soy infant formula.”

Sue Kedgley and Mike Fitzpatrick were asked if they were hopeful something productive might come out of this review.

Dr Fitzpatrick says he feels hopeful. “That label is very important.

“I am pleased that they would look at it and not be subject to industry pressure. I mean, that was my concern all along that the industry is really strong, lobbying governments, government agencies and very good at putting pressure on individuals. We felt that pressure but it’s good that even if it is 10 or 15 years later it’s good that the FSANZ is looking at it.”

And while the former Greens MP had earlier been critical of the Government’s attitude to labeling as just a “marketing tool rather than something to impart information to consumers”, she is also optimistic.

“I think it is promising that they are reviewing the guidelines. It seems that it has taken them an awfully long time to do so, but I just hope they take a Precautionary Principle.”