FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Information Brief

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To: Assistant Minister Gillespie

Subject: Nanoparticles in infant formula

Purpose: To update the Minister on recent media enquiries on the Friends of the Earth (FoE) commissioned survey of Australian infant formula products.

Clearance:

Contact Officer:	*Gillian Duffy*	*Senior Nutritionist, Public Health Nutrition Standards Section, FSANZ*	[redacted]
Clearance Officer:	*Mark Booth*	*CEO, FSANZ*	[redacted]

Key Issues:

1. On 14 June 2017, FSANZ received a media request from *The Sydney Morning Herald* to respond to the results of a study commissioned by Friends of the Earth Australia (FoE). The results were previously provided to FSANZ by the ABC in an earlier media request (May 2017).
2. The information provided to FSANZ claimed that nanoscale hydroxyapatite, calcite, silicon, and oxygen particles were detected in five of seven products tested. The results also noted that some of the nano hydroxyapatite particles were a needle-like shape, others were rectangular in shape. The results also claim that titanium and silicon were found in all seven products.

Background:

The recent media enquiry is focused on the presence of 'needle shaped hydroxyapatite nano particles', suggesting these are engineered and deliberately added to some infant formula without a pre-market safety assessment. The limited information provided to FSANZ does not enable us to determine whether the particles found in the study are produced naturally, during manufacture or added intentionally.

The FoE-commissioned report has not been peer-reviewed and sufficient detail has not been provided to enable FSANZ to conduct an independent evaluation. However, there is no reason to suggest that a public health and safety concern exists based on the information provided. In particular, there is no evidence that the trace amounts of calcium- and phosphate-containing minerals (with nanoscale dimension) found in this study pose a health and safety concern when ingested.

The concerns regarding the 'needle shape' are based on the conclusions of an EC Scientific Committee on Consumer Safety (SCCS) opinion on hydroxyapatite. FSANZ considers this report to be of limited relevance to the detection of trace amounts of hydroxyapatite in the FoE-commissioned study. The Opinion considered that insufficient information had been provided by applicants to enable a conclusion on safety when used in toothpaste, whiteners, and mouth washes.

FSANZ sought independent scientific advice from members of our Scientific Nanotechnology Advisory Group which advised that the information provided does not indicate these products might pose a public health and safety risk.

The Australian Science Media Centre also provided FSANZ with a copy of the comments which they provided to the Sydney Morning Herald (refer to Attachment).

FSANZ has liaised with the Infant Nutrition Council and individual infant formula companies. All companies we have been able to contact have advised that engineered nanoscale materials are not intentionally added to infant formula.

Limitations of the information provided to FSANZ

Arizona State University reported the detection of some nanoscale hydroxyapatite and calcite particles in some infant formula products. While the results have detected individual particles, the method is unable to provide useful information for risk assessment, because it does not measure the amount of the substance in the tested products. However, FSANZ considers that the detection of small amounts of these materials is unlikely to pose a health concern. FSANZ notes:

- Hydroxyapatite is a naturally-occurring mineral that makes up a significant component of bone. It provides structure and strength to teeth and bone and provides a reservoir of calcium that helps maintain a constant concentration of calcium in the blood. It is widely used as a source of calcium in health supplements. Hydroxyapatite is soluble in acidic environments such as the stomach, so it can be reasoned that small amounts in food will likely dissolve and release its calcium.

- Calcium and phosphorus are essential minerals and are required in infant formula. Several chemical forms of these two minerals are permitted additives to infant formula.

- Titanium and silicon are widely used internationally in a range of food products and have been used safely as food additives for decades. A review commissioned by FSANZ in December 2014 to an expert toxicologist, Dr Roger Drew, found that there is currently no reasonable evidence to support that titanium dioxide or silicon dioxide pose a risk to health and safety when used in foods.

Further information on the levels of titanium, silicon and hydroxyapatite in the tested products would be required for FSANZ to provide a more definitive assessment.

Safety/regulatory requirements for infant formula in Australia

All infant formula products sold in Australia and New Zealand must be safe and comply with the *Australia New Zealand Food Standards Code* (Code). Infant formula products are regulated under Standard 2.9.1 – Infant formula products and Schedule 29. The Code prohibits the use of food additives, nutritive and novel substances in infant formula, unless they are expressly permitted. The Code requires new food additives, nutritive and novel substances proposed to be used in infant formula to undergo a pre-market safety assessment.

Nanoparticles in infant formula and food

Nanoscale materials are not new. Food is naturally composed of nanoscale sugars, amino acids, peptides and proteins, many of which form organised, functional nanostructures. For example, proteins are in the nanoscale size range and milk contains an emulsion of nanoscale fat droplets. Humans, including infants, have consumed these particles in foods throughout evolution without evidence of adverse health effects related to the materials' nanoscale size.

The focus of FSANZ in regulating nanoscale materials in food is not on size *per se*, but rather the potential for materials to exhibit physical or biological novelty. Food substances that involve the use of nanotechnology require pre-market approval if the particle size is important to achieving the technological function, or may relate to a difference in toxicity.

Attachment:

1. Expert comments from the Australian Science Media Centre

Attachment 1: Expert comments from the Australian Science Media Centre

Adjunct Professor Andrew Bartholomaeus is a consultant toxicologist with Adjunct Professor appointments at the University of Canberra and the University of Queensland. He has previously been the Chief Toxicologist for the Therapeutic Goods Administration and the General Manager of the Risk Assessment Branch of FSANZ.

"The Friends of the Earth slide deck presents the rather unexciting and facile observation that a food containing high levels of calcium and phosphate and undergoing a variety of processes during production has a small quantity of calcium phosphate crystals (Ca apatite).

Regardless of the provenance of the observed material, calcium apatite is a normal human component of teeth and bones and small quantities of nanoparticulate deposits of this material can be found in normal human tissue.

Calcium apatite is also soluble in acidic conditions so the small quantity of the material present in infant formula would dissolve into essential nutrients and cease to be nano.

Similarly, silicon dioxide has been used as an ingredient of food, cosmetics, pharmaceuticals and a wide range of other products for the better part of a century without evidence of adverse health effects and the very low levels claimed to be present in the formula are highly unlikely to present a human health risk.

There is no evidence to indicate that nano dimensions of particulates are of themselves a risk to human health, and normal human breast milk is composed of a nano material (casein protein agglomerates).

Nano particulate materials form naturally in the gut due to the action of the intestinal microbiome and the commercial production of some nanoparticulate metals utilises this process. Consequently, small quantities of nanoparticulates are a normal aspect of the human diet and present no basis for concern.

One would hope that Friends of the Earth have sufficient moral compass to not seek to exploit the natural concern of mothers for the health of their children to further their corporate objectives by scaremongering analytical findings of no especial significance."

Dr Ian Musgrave is a Senior Lecturer in the Faculty of Medicine, School of Medicine Sciences, within the Discipline of Pharmacology at the University of Adelaide

"Nanoparticles have become the latest boogeyman, despite nanoparticles occurring naturally. The PowerPoint presentation “Detecting Engineered Nanomaterials in Australian Procured Infant Formula” fails to put nanoparticles in their natural biological context, or to provide any significant support that particles detected in milk are engineered nanomaterials.

Infant formula is based on milk, which naturally contains calcium and phosphorus (as phosphates). The calcium and phosphates are in a complex balance between soluble and protein-bound forms.

One of the forms of calcium phosphate in milk is hydroxyapatite. So it is unsurprising that hydroxyapatite is found in dried infant formula which is predominantly dried milk powder. Experiments with drying milk have found that nanometre-sized particles of calcium phosphate form naturally. The health effects of hydroxyapatite nanoparticles have been studied in animals with no toxicity at levels well above those present in milk.

There are no significant public health implications for the finding of small crystals of naturally occurring calcium phosphates in milk-based products."

Dr. Emad Kiriakous is a Senior lecturer in nanotechnology and molecular sciences at the Queensland University of Technology

"The use of nanotechnology and nanomaterials in food products is increasing worldwide. It is inevitable that intended and unintended human exposure to nanomaterials will increase. Some nanomaterials are toxic to animals and humans. Therefore, the current regulations of food nanotechnology should take into account the risk characteristics of nanomaterials used in the food industry.

The presence of nano silicon and oxygen particulates in Australian Infant Formula is not alarming. Silicon dioxide and silicates have had a history of use in food without detrimental effects. However, the presence of needle shaped hydroxyapatite nanoparticles in infant formulas is significant since there is growing scientific evidence that the cytotoxicity of hydroxyapatite nanoparticles is shape- and cell-dependent.

Recent research has shown that hydroxyapatite nanoparticles of needle-like geometry cause cell-specific cytotoxicity.

Many international regulatory agencies have issued guidance documents with respect to the potential risks posed by nanomaterials. Therefore, with the recent findings by Arizona State University, it is important that Food Standards Australia New Zealand (FSANZ) setup comprehensive guidelines for the food industry on nanomaterials, their safe shape and size, and their potential intestinal uptake and cytotoxicity. It is very important to commit the food industry to using only safe nanomaterials."

Professor Ian Rae is is an expert on chemicals in the environment and is an Honorary Professorial Fellow in the Faculty of Arts at the University of Melbourne. He is also an advisor to the United Nations Environment Programme on chemicals in the environment.

"This is a classical NANO SCARE. The clue that the investigators are pushing an agenda is in their repeated use of the phrase 'needle like' to describe the crystals of hydroxyapatite. It's a 'dog whistle' for 'you will be feeding your babies sharp objects if you use these products'.

The truth is that these particles are the natural form of hydroxyapatite and they dissolve easily in the acids of the digestive system. Moreover, the particles are extremely small - much smaller than the diameter of a human hair - and they make up a tiny proportion of the products.

The use of all that analytical chemical firepower might serve to over-awe the non-expert reader. Anyone who understands them and can assess the numbers will just ask 'so what?'."