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 inform the Minister of a Friends of the Earth (FoE) commissioned survey conducted by Arizona State University which tested seven Australian infant formula products.

Clearance:

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Key Issues:

1. On 4 May 2017, FSANZ received a media request to respond to the results of a study commissioned by Friends of the Earth Australia (FoE). The results 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.

2. We expect the FoE messaging to suggest there is a risk to infant health and safety based on the following assertions: that engineered nanoscale materials are being deliberately added to infant formula; some of the nanoscale material is in a needle like shape; and unpermitted minerals are being added to infant formula.

3. The FoE commissioned report has not been peer-reviewed and sufficient detail has not been provided for FSANZ to conduct an independent evaluation. However there is no reason to suggest that there is a public health and safety concern 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.

4. FSANZ is liaising with the Infant Nutrition Council and individual infant formula companies. All companies have advised that engineered nanoscale materials are not being intentionally added to infant formula. We are also in the process of seeking advice from our scientific advisory group and will be providing information to the Jurisdictions.

Background:

Limitations of the information provided to FSANZ

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.

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 is 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.

2016 United States FoE-commissioned study of nano in infant formula

In 2016, FoE commissioned Arizona State University to study six infant formulas available on the US market. This also reported the detection of titanium, silicon and hydroxyapatite particles in some infant formula products. The results were released globally and were used in an email campaign to Ministers in Australia in May 2016. One focus of the FoE campaign

was a conclusion of the EC Scientific Committee on Consumer Safety (SCCS) opinion on hydroxyapatite.

This scientific opinion considered data provided by an applicant to evaluate safety of hydroxyapatite in cosmetic products. The conclusion that insufficient information had been provided to determine safety when used in oral cosmetic products (e.g. toothpaste, whiteners, mouth washes) at levels of up to 10% is of limited relevance to the detection of trace amounts of hydroxyapatite in food. The report did not consider oral consumption of hydroxyapatite, which is soluble in acidic environments such as the stomach. Thus small amounts in food are likely to dissolve to release calcium and phosphate.