

Fletcher, Nick

From: Andrew Bartholomaeus <[REDACTED]>
Sent: Wednesday, 21 June 2017 8:56 PM
To: Fletcher, Nick
Subject: Re: FW: FW: Proposed different approach [SEC=UNOFFICIAL]

thanks nick

I sent you a BCC of my response to esther. will let you know how it goes.

Cheers

Andrew

On 21 June 2017 at 15:07, Fletcher, Nick <[REDACTED]> wrote:

Hi Andrew – this what has been provided to Esther so far. Sorry for the delay – been in Board.

Nick

From: Media
Sent: Wednesday, 21 June 2017 12:54 PM
To: Fletcher, Nick
Subject: FW: FW: Proposed different approach [SEC=UNOFFICIAL]

Our responses to Esther below SMC's response

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 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?'."

From: Media
Sent: Wednesday, June 14, 2017 2:50 PM
To: 'Esther Han'; Media
Subject: RE: FW: Proposed different approach [SEC=UNOFFICIAL]

The needle-like shape of particles is unlikely to present a significant hazard given they are likely to dissolve in the stomach. Any safety issues would be related to the constituent components, in this case calcium and phosphate. These are considered beneficial and required to be added to infant formula.

From: Esther Han [REDACTED]
Sent: Wednesday, June 14, 2017 1:16 PM
To: Media
Subject: Re: FW: Proposed different approach [SEC=UNOFFICIAL]

Thanks Lorraine, confirming I've received FSANZ's response.

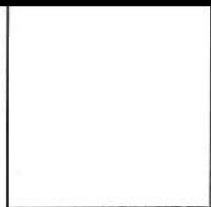
It's really interesting that it doesn't once refer to "needle-like nano hydroxyapatite", which I referred to dozens of times in my media request.

Esther

Esther Han

Consumer Affairs Editor

The Sydney Morning Herald | The Sun-Herald
1 Darling Island Road, Pyrmont, New South Wales, 2009



On 14 June 2017 at 13:11, Media <Media@foodstandards.gov.au> wrote:

Hi Esther

We have provided a statement below. FSANZ is concerned that an extremely vulnerable section of the community will be unnecessarily scared by this work and we therefore would appreciate balanced reporting on this issue.

FSANZ statement in response to nanoparticle detection in infant formula

FSANZ scientists (along with experts who make up an expert advisory group on nanotechnology) have examined the data provided in the PowerPoint. The findings do not contain any new information to suggest that these products might pose a public health and safety risk.

FSANZ takes concerns about food safety extremely seriously. FSANZ does not believe that there is a risk to infant health and safety.

Hydroxyapatite is a mineral. It is a natural component of bone and teeth. It is a source of calcium and phosphate, and small amounts in food are likely to readily dissolve in the stomach to release these minerals which are beneficial when absorbed. Both calcium and phosphate are required to be in infant formula as nutritive substances.

The presence of a substance in food (regardless of size), that is not in the additive schedule, does not mean there is a safety concern. Particles (nanoscale or otherwise) could be present in food unintentionally as a result of food processing techniques. Nanoparticles also occur naturally and can be found in foods.

The EC Scientific Committee on Consumer Safety (SCCS) opinion on hydroxyapatite considered that the information provided by applicants was insufficient to draw a conclusion on safety when used in oral cosmetic products (e.g. toothpaste, whiteners, mouth washes) at levels of up to 10%. In reaching this conclusion, the SCCS noted that the hydroxyapatite materials under consideration could not clearly be related to the data submitted.

The SCCS report is considered of limited relevance to the detection of trace amounts of hydroxyapatite in the FoE-commissioned study of infant formula.

Several of your questions relate to enforcement and compliance. FSANZ is not an enforcement agency and does not have the power under its legislation to initiate a recall.

Lorraine Haase

Manager

Communication and Stakeholder Engagement

[Redacted]

[Redacted]

www.foodstandards.gov.au

55 Blackall Street, Barton, ACT 2600

PO Box 5423, Kingston ACT 2604



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Prof (Adj) Andrew Bartholomaeus
School of Pharmacy, University of Canberra
Therapeutic Research Unit, School of Medicine, University of Queensland

