From:	Fletcher, Nick
To:	Berven, Leise; Haase, Lorraine; Webb, Trevor; Crossley, Steve
Cc:	Crerar, Scott
Subject:	FW: Needle-like nano hydroxyapatite [SEC=UNCLASSIFIED]
Date:	Thursday, 22 June 2017 8:25:28 AM
Attachments:	~WRD000.jpg

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fyi
From: Andrew Bartholomaeus [mailto[redacted]]
Sent: Wednesday, 21 June 2017 8:42 PM
To: Esther Han
Subject: Re: Needle-like nano hydroxyapatite
Esther

Thanks for your enquiry. My apologies for a rather long winded response below but the technique employed by FoE and other NGOs on a mission, is to confound issues by trying to make the relatively simple look complicated and seeking to create the appearance of conflict of opinions where there are none. So I have attempted to work through the key issues for you.
So, allow me start with a few basics. Everything is toxic by some route under some conditions at some dose, even oxygen and nitrogen in the air we breathe.That nitrogen at a pressure greater than 40 mtrs of water cause inebriation and unconsciousness does not mean we ban driving whilst breathing. That something presents an unacceptable, or unknown or inadequately demonstrated risk at a high exposure does not mean the same is true at minuscule exposures.

A hallmark of many activist groups seeking to expand their support base and cash flow is to take information out of context and create false contradictions to generate outrage. The fact for example that the SCCS has indicated they have concerns about hydroxyapatite in oral cosmetics at high exposures - due largely to questions about the adequacy and relevance of the data submitted in support of the application rather than perceived hazard- does not mean that a hazard is expected to exist from low levels of naturally forming material in infant formula or that their conclusions are contradictory with those of FSANZ. The discordance is a matter of context not substance, as FoE well know.

Similarly the deliberate addition of significant amounts of hydroxyapatite - nano or otherwise to infant formula might be postulated to be of concern when minuscule quantities formed naturally during processing may clearly be of no concern. There is no discordance in these two positions. Hydroxyapatite dissolves in acid conditions such as the stomach so small quantities would simply provide calcium for bone growth. Large exposures through deliberate addition might be postulated to present a risk due to survival of a proportion of the exposure through the stomach acid, although I doubt it. Even so, hydroxyapatite crystals form naturally in systemic (ie internal) tissues (they were once postulated to be nano-bacteria until chemically characterised). Given that the crystals will dissolve in the stomach their size and shape is irrelevant. Even if they did not dissolve, a large number of pharmaceutical companies would pay very large sums if anyone could get quantitative absorption of nano (or any) particulates into the systemic circulation, so the bulk of any nano particles getting to the intestines would pass out in the faeces. If tiny quantities did get absorbed they would be processed in the tissues in the same way that naturally occurring hydroxyapatite crystals are processed in our bodies. Nano and other forms of hydroxyapatite are used as implant materials in human surgery to repair bone defects - ie they are directly inserted into the body and are not toxic or hazardous - I have evaluated some of these.

While one or another crystal shape may be the most common naturally produced, compared to synthetically produced, crystals this does not equate to a conclusion that the synthetic crystal form is more hazardous. If the material dissolves in biological fluid (as it does) the crystal shape is irrelevant following dissolution. Also, while synthetic processes may well be required to produce a pure bulk amount of the needle like crystals this does not mean that the needle like crystals do not form naturally, merely that they are a small proportion of the crystals formed. So again, context and precision of expression matters. There is no doubt that crystal shape and structure can make a difference in the toxicity of particulates *under some specific circumstances*. If the cytotoxicity of a particulate is determined in cell culture (ie test tube) the shape and structure may cause more or less toxicity *but* cell culture with very high exposures of unprotected cells does not reflect the real

world of very low level exposure via the gut and the two are simply not comparable in any intellectually genuine sense.

All manufacturing will produce particulates some of which will be nano. Just rub two surfaces together and nano particulates are generated. Human breast milk is a nano food and so is ice cream. So nano-ness *per se* is largely irrelevant in most circumstances (eg not true for inhalation once lung clearance rates are saturated or where crystal form and shape prevent clearance/dissolution).
The various processes in producing milk powders in infant formula would be expected to have potential to generate the minuscule amounts of hydroxyapatite seen in the infant formulas analysed.
So;

1. the hydroxyapatite has not been deliberately added given the tiny quantities involved and it is not "synthetic" in the sense of being deliberately generated
2. The precise provenance (ie how and where it came from) is not a pertinent issue if it has not been deliberately added and does not pose a risk.
3. It may be that the processing steps used in the processing of milk powder (which contains the building blocks of hydroxyapatite) has resulted in the generation of a tiny quantity of particulate hydroxyapatite crystals – this is highly likely
4. FSANZ is 100% correct. Misapplication of the precautionary principle based on confected outrage is risk generating, not risk mitigating. Regulatory agencies have both a legal and moral responsibility to act on the overall weight of evidence, rather than extreme speculation from questionable sources, and in this case FSANZ has done exactly that (ie they have followed the weight of evidence).
5. the juxtaposition of the SCCS conclusions regarding addition of substantial quantities of needle like hydroxyapatite to oral cosmetics against the finding of minuscule quantities of the material in infant formula is invalid other than as a cheap rhetorical device to generate faux outrage (actually I guess the outrage is real but the basis is faux)
6. The precautionary principle is not precautionary if its application creates harm greater than the postulate risk. In this respect, I have a personal aversion to any level of risk in infant formula - both my children were adopted as babies and infant formula was the only nutrition available for them. So if I thought there were a real issue I would be the first to be clamoring for action. More generally many mothers cannot breast feed despite their best efforts and use of milk from other women through unofficial channels, even if available, is not without significant potential risks. So, infant formula is needed and the incidental formation of minuscule levels of a non-toxic (at the levels found) normal nutritional material, that ceases to be particulate in the stomach, is immaterial. Demonizing infant formula, and exploiting the guilt felt by many mothers who have no option but to use formula, for any reason, has the potential to do harm far greater than any risk from the tiny amounts of hydroxyapatite reported in the FoE papers.

Th**e SCCS and Professor Westerhoff say that needle-like nano hydroxyapatite is man-made and not naturally occurring. Nestle says "needle-like nano hydroxyapatite particles occur naturally and may also be generated in small quantities in processing in the presence of calcium and phosphorus, both of which are in milk and are required components of infant formula."**

Both are quite likely correct. bone and other naturally occurring hydroxyapatite may not contain significant quantities of the needle like crystals but as Nestle state if you manipulate solutions containing calcium and phosphorous during production of milk powders the formation of needle like hydroxyapatite in minuscule quantities is likely to occur naturally. So, there is not necessarily any discordance. In any event the issues is moot if the crystals dissolve in the stomach because they then become one in the same material regardless of the original crystal structure.

Is needle-like nano hydroxyapatite different (apart from shape) to non-nano or rectangular-shaped hydroxyapatite? How so? Or is it the same?
Once a crystal dissolves the shape prior to dissolution is irrelevant. The minuscule quantities identified in the milk formula would readily dissolve. Ironically in the current context, the smaller the size of the particles the greater the surface area and therefore the more rapid the dissolution- so the nano size **REDUCES** the risk if there actually were any.

There are circumstances where crystal form does matter such as the inhalation of particulates noted above and in the highly artificial environment of cell culture but not generally in the case of oral ingestion other than in terms of dissolution rate – as noted above.

The real story here is the cynical attempt to manipulate the media, the guilt of many mothers needing to use infant formula in a “Breast is Best” environment (and if you can do, it is best) and of public opinion, by disingenuous rhetorical devices intended to generate publicity but of no relevance to public (or infant) health. The approach has become the hallmark of Greenpeace and friends of the earth. This is something recently exposed in Canada by a case brought against Greenpeace by a company persistently slandered by that organisation. In defending their rhetoric the counsel for Greenpeace submitted to the court that their public statements “**do not hew to strict literalism or scientific precision,” but rather should be seen as “hyperbole,” “heated rhetoric,” and “non-verifiable statements of subjective opinion” that should not be taken “literally”** (Garneau, 2017 -http://www.nationalreview.com/article/445373/greenpeace-environmental-groups-sued-resolute-forest-products-ontario-quebec). Well there's a revelation ! Whether this is also true for FoE in the current context is matter of judgement.

Commercial entities, like individuals and NGOs, can and do make errors of judgement and allow their personal conflicts of interest to compromise their actions - the manipulation of emissions readings by Volkswagen and the past behaviour of the Banks in their financial advice are classic examples. Commercial entities however, quite rightly, have a raft of legal, regulatory and financial constraints on such action which can and do result in substantial damage to the entity and its shareholders when they transgress. NGOs however have all of the conflicts but none of the constraints as the Greenpeace admission in court amply demonstrate.
Hope this has been of some assistance
Regards
Andrew
On 21 June 2017 at 13:21, Esther Han <[redacted]> wrote:
Hi Andrew,
No worries, today CoB/tomorrow morning is fine. Looking forward to receiving your response,
Kindest regards
Esther

Esther Han
Consumer Affairs Editor
The Sydney Morning Herald | The Sun-Herald
1 Darling Island Road, Pyrmont, New South Wales, 2009
[redacted]

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On 21 June 2017 at 13:18, Andrew Bartholomaeus <[redacted]> wrote:
Esther

I will get you something today but may be a bit after COB. I don't have quite the resources to apply to these issues that FoE or FSANZ have.

Regards

Andrew
On 21 June 2017 at 11:29, Esther Han <[redacted]> wrote:
Hello Andrew,
Hope you're well. I'm a journalist at the Sydney Morning Herald and I'm working on a story based on research, commissioned by Friends of the Earth, that found needle-like nano hydroxyapatite in two infant formula products sold in Australia.

To be clear, I'm focusing largely on needle-like nano hydroxyapatite and two products: Nature's Way Kids Smart 1 and Nestlé NAN H.A. Gold, not generally on nanoparticles. I've attached a couple of documents (which I'm sure you've already seen) - one from Professor Paul Westerhoff at Arizona State University and one from the European Union's Scientific Committee on Consumer Safety.
My questions below are based on these two documents, plus statements from FSANZ and the companies, as well as your reaction (sent earlier via SMC).
- The SCCS and Professor Westerhoff (as well as other experts - please see the third attachment) say that needle-like nano hydroxyapatite is man-made and not naturally occurring. Nestle says "needle-like nano hydroxyapatite particles occur naturally and may also be generated in small quantities in processing in the presence of calcium and phosphorus, both of which are in milk and are required components of infant formula." What is your position? Is it man-made or naturally occurring?
- Is needle-like nano hydroxyapatite different (apart from shape) to non-nano or rectangular-shaped hydroxyapatite? How so? Or is it the same?
- The EU study concluded that "The available information indicates that nano-hydroxyapatite in needle-shaped form is of concern in relation to potential toxicity. Therefore, needle-shaped nano-hydroxyapatite should not be used in cosmetic products." (P35 of 2nd attachment). What is your reaction? Isn't it fair for consumers to conclude that the precautionary principle should be applied and more studies should be undertaken to see how it may affect people's health? Or do we know enough about it?
- Should the precautionary principle be applied in this case, and products containing needle-like nano hydroxyapatite be taken off shelves? Why or why not?
- FSANZ says : "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." It also says "The SCCS report is considered of limited relevance to the detection of trace amounts of hydroxyapatite in the FoE-commissioned study of infant formula." What is your opinion on this response? Is it adequate and sufficient?
- FSANZ, in a nutshell, says there is nothing to worry about. Is this response appropriate and sufficient, given it must follow the ministerial policy guideline which states that a pre-market assessment should be required for any substance proposed to be used in infant formula that doesn't have a history of safe use or has a history of safe use but has a different form/structure, or is produced using a substantially different technique or technology?
- Your SMC statement refers to "calcium apatite". To confirm, is your statement only applicable to nano calcite? Is your position and statement applicable to rectangular shaped nano hydroxyapatite and needle-like nano hydroxyapatite?
- Any other comments?
DEADLINE: Wednesday CoB (today), please let me know if you need more time.
Kind regards
Esther
Esther Han
Consumer Affairs Editor
The Sydney Morning Herald | The Sun-Herald
1 Darling Island Road, Pyrmont, New South Wales, 2009
[redacted]

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

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