From: Booth, Mark
To: Media
Cc: Crossley, Steve; Webb, Trevor; May, Peter; Fletcher, Nick; Berven, Leise; Duffy, Gillian; Lewis, Janine
Subject: Re: URGENT MEDIA REQUEST SMH Nano and infant formula [SEC=UNOFFICIAL]
Date: Wednesday, 14 June 2017 11:45:08 AM
Attachments: image008.png
image009.png
image010.jpg
image001.png
image002.png

Can you talk me through this at lunch break - 12.45

Sent from my iPhone

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

Hi all – particularly Trevor/Mark/Peter for clearance
After discussing this with Peter this is our proposed approach
We will send the following:
Hi Esther please see attached (and below) [redacted] Please note
FSANZ has no authority to initiate a recall (we are not an enforcement agency)
[redacted]

[redacted]

[redacted]

Lorraine Haase
Manager
Communication and Stakeholder Engagement
[redacted]
www foodstandards gov au
55 Blackall Street, Barton, ACT 2600
PO Box 5423, Kingston ACT 2604

From: Crossley, Steve
Sent: Wednesday, June 14, 2017 10 06 AM
To: Media; Webb, Trevor; May, Peter; Fletcher, Nick; Berven, Leise; Duffy, Gillian; Lewis, Janine; Fitzroy, Mark
Subject: RE URGENT MEDIA REQUEST SMH Nano and infant formula [SEC=UNOFFICIAL]
Dear Lorraine
I have added a number of edits Please also see my comment 1 which is important
Thanking you
Kind regards
Steve C

From: Media
Sent: Wednesday, 14 June 2017 9 32 AM
To: Media; Webb, Trevor; May, Peter; Fletcher, Nick; Berven, Leise; Duffy, Gillian; Lewis, Janine; Crossley, Steve; Fitzroy, Mark
Subject: RE URGENT MEDIA REQUEST SMH Nano and infant formula [SEC=UNOFFICIAL]
Hi everyone
Draft response is saved here for editing/comment
http://fsintranet/Sections/case/Documents/Community%20Relations/Media%20relations/Comms%20plans/Nanotechnology/Nano%20enquiry%20draft%20response docx

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From: Media
Sent: Tuesday, 13 June 2017 6 07 PM
To: Webb, Trevor; May, Peter; Fitzroy, Mark; Fletcher, Nick; Berven, Leise; Duffy, Gillian; Lewis, Janine; Crossley, Steve
Cc: Media; Polegubic, Veronica
Subject: URGENT MEDIA REQUEST SMH Nano and infant formula [SEC=UNOFFICIAL]
Importance: High
I have started a response
See below for checking/adding and clearing (yellow parts needs some words) that I will review Please note we need to keep our responses simple I will discuss with Peter/Trevor and Mark tomorrow
Gill/Janine/Leise – as discussed we need the web page cleared asap Given Esther's previous reporting I would like something cleared by COB tomorrow in anticipation
Lorraine Haase
Manager
Communication and Stakeholder Engagement
[redacted]
www foodstandards gov au
55 Blackall Street, Barton, ACT 2600
PO Box 5423, Kingston ACT 2604

From: Esther Han [redacted]
Sent: Tuesday, June 13, 2017 5 22 PM
To: Media
Subject: Nano-hydroxyapatite
Hello,
I'm working on a story for the SMH about the presence of nano-hydroxyapatite in infant formulas sold in Australia. Please see the report by Professor Paul Westerhoff of Arizona State University (will attach to follow up email). It was commissioned by Friends of the Earth Australia.
I'm not writing generally about nanoparticles (so please don't provide generic answers that refer to nanoparticles), but I'm focusing on needle-like nano hydroxyapatite.
The key points are
- Professor Westerhoff, using state of the art technology, found that needle-like nano hydroxyapatite is present in two infant formulas Nature s Way Kids Smart 1 and Nestlé NAN H.A. Gold.
- It is agreed and known that needle-like nano hydroxyapatite is synthetic/man-made. It is not naturally occurring.
- The European Union s Scientific Committee on Consumer Safety has 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).
- The Ministerial Policy Guideline (third attachment) says "Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology."
Hi Esther answers to your questions below It is very important to note that the presence of something in any food that does not have a permission as an

additive does not necessarily mean there is a safety concern FSANZ is concerned that an extremely vulnerable section of the community will be unnecessarily scared by this work and we would therefore would appreciate balanced reporting on this issue
We understand the ABC has contacted independent experts who have reiterated FSANZ's position on this data as have independent experts who make up an expert advisory group on nanotechnology
The Australian Science Media Centre also has experts ready to respond if you require responses from elsewhere You have included a question about our web page This is being updated in anticipation of media and to reassure consumers
My questions to FSANZ (specifically concerning needle-like nano hydroxyapatite) are
- Is needle-like nano hydroxyapatite allowed to be in infant formula sold in Australia? If yes, please tell us how and why.
While this is not permitted as a food additive, the presence of hydroxyapatite nanoscale particles does not represent a safety concern This is the case for any food The presence of something not permitted as an additive does not in itself represent a safety issue FSANZ and independent experts have reviewed the data and concluded there is no safety issue
Hydroxyapatite is soluble in acidic environments like the stomach Small amounts in food are likely to dissolve to release calcium and phosphate and these are both essential minerals and required in infant formula products (as nutritive substances in the Infant Formula Standard)
- If no, why is infant formula containing needle-like nano hydroxyapatite being sold in Australia?
It is possible that these particles may be present due to a processing technique FSANZ and independent experts have reviewed the data provided and have concluded there are no safety concerns relating the presence of these particles You may like to speak to the infant formula manufacturers about how they may be in the product
- FSANZ now has a copy of a report showing that needle-like nano hydroxyapatite is present in two infant formula products. How will it respond?
FSANZ has responded by investigating what has been provided Based on what has been provided FSANZ has no safety concerns This information has also been provided to jurisdictions who enforce the Code
- Does FSANZ doubt the conclusions of the ASU report? Why or why not?
The report presents no conclusions It is a report on the presence or absence of nanoscale particles in the products The results have not been published or peer reviewed Based on what has been provided FSANZ does not believe there is a safety issue As discussed with you previously FSANZ is not an enforcement authority We have provided the data to jurisdictions for information
- Will FSANZ conduct its owns tests to see whether the ASU results are accurate? Why or why not?
Given the presence of these particles does not represent a safety concern FSANZ will not conduct further tests FSANZ has no enforcement powers
- Will FSANZ conduct its own scientific literature review on needle-like nano hydroxyapatite to determine whether it is safe to be consumed, especially by infants? Why or why not?
FSANZ has established an expert advisory group on nanotechnology The experts on this group (like the expert toxicologists in this field at FSANZ) have concluded there is no safety issue
- The SCCS concluded that needle-like nano hydroxyapatite should not be used in cosmetic products. Yet, tests show it is present in two infant formula products sold in Australia. Do parents have the right to be concerned or alarmed? Or should they continue feeding their children the two products?
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 report is considered of limited relevance to the detection of trace amounts of hydroxyapatite in the FoE-commissioned study of infant formula
There is absolutely no cause for concern relating to these findings
- What is FSANZ's position on the SCCS' conclusions about the safety of needle-like nano hydroxyapatite?
See above
- There are safety concerns about needle-like nano hydroxyapatite. Is needle-like nano hydroxyapatite considered to be a new, non-traditional, novel food? Why or why not? Has permission been granted for it to be included in infant formula?
- Does needle-like nano hydroxyapatite need to undergo a safety assessment so that FSANZ can determine whether it can be legally supplied in Australia? Please explain this process.
- If the companies claim and truly believe that needle-like nano hydroxyapatite is not added to or not contained in their infant formula products, would FSANZ simply accept this? Or will it verify these claims?
See our response re enforcement Today's manufacturing processes could result in small amounts of nanoscale particles being present This does not in itself represent a safety concern
- Is it possible that the companies are unaware that needle-like nano hydroxyapatite is present in their infant formula products? Perhaps needle-like nano hydroxyapatite was unknowingly added by someone in the supply chain? Is it possible that they do not know, and therefore they're selling products containing needle-like nano hydroxyapatite whilst making claims to the contrary?
You will need to speak to the infant formula industry on this but our comment on manufacturing processes applies
- Is it reasonable for the average person, after reading about the availability of infant formula containing needle-like nano hydroxyapatite in Australia, to believe and conclude that food safety regulation is weak and full of loopholes?
It is not reasonable for the average person to reach this conclusion
- Is it fair and understandable for the average consumer to expect FSANZ to conduct its own tests to see whether needle-like nano hydroxyapatite is present in infant formula, and for the results to be made public? Why or why not?
FSANZ isn't an enforcement agency We have explained how the food regulation system works but I have included a link to help explain who does what http://www foodstandards gov au/about/safefoodsystem/Pages/default aspx
- Can FSANZ confidently state that the consumption of foods and a child's consumption of infant formula containing needle-like nano hydroxyapatite are safe? If it's unsure or cannot yet provide an answer, what will it do so that one day it can?
FSANZ can reassure all consumers there is no safety issue in relation to these findings and will be actively reassuring consumers by providing website information if the story is published
- Is FSANZ's response appropriate and sufficient, given it must follow the ministerial policy guideline which state 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?
Experts in toxicology have reviewed this data and concluded there are no safety concerns It is important to stress that the presence of any particle (nanoscale or otherwise) that doesn't have a specific permission in the food additives standard does not mean there is a safety issue
- FSANZ's webpage "Nanoparticles and Infant Formula", published May 2016, has been removed. When, why, and will it be republished? What changes will be made?
We are updating this page based on the information provided to us by another reporter The information is being updated in anticipation of news media about this data and to provide reassurance to consumers
- FoE want FSANZ to initiate a recall of infant formula products with needle-like nano hydroxyapatite. How does it respond?
We are not an enforcement agency
- Any other comments?

<!--[if !supportLists]-->o <!--[endif]-->Hydroxyapa ite 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.

<!--[if !supportLists]-->o <!--[endif]-->Calcite has low solubility in he gastrointestinal tract regardless of whether it is in nanoscale form or larger particles, but the small fraction that is absorbed is likely to be in the form of calcium.

<!--[if !supportLists]-->o <!--[endif]-->Silicon dioxide has been used safely as a food additive in other foods in Australia, and internationally, for many years.

Does FSANZ believe the needle-like form of nano-hydroxyapatite is safe, considering that the European Commissions's Scientific Committee on Consumer Safety has concluded that it's potentially toxic and should not be permitted in oral products like toothpaste and mouthwash?

<!--[if !supportLists]-->● <!--[endif]-->There is no evidence that the trace amounts of nano-hydroxyapatite reported in the FoE report pose a health and safety risk when ingested. Hydroxyapatite is soluble in acidic environments such as the stomach, so small amounts in food are likely to dissolve to release calcium and phosphate. These are both essential minerals and required in infant formula products.

<!--[if !supportLists]-->● <!--[endif]-->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.

<!--[if !supportLists]-->● <!--[endif]-->The report is considered of limited relevance to the detection of trace amounts of hydroxyapatite in the FoE-commissioned study of infant formula.

DEADLINE I understand FSANZ is in possession of Professor Westerhoff's report and is across all the issues. Therefore, 24 hours should be sufficient, that is, Wednesday CoB. If there are any issues, please let me know. If FSANZ can't answer some of the questions because they should instead be sent to enforcement authorities, please let me know ASAP.
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]