

The Hon David Bennett MP  
Minister for Food Safety  
Member Australia and New Zealand Ministerial Forum on Food Regulation

3 July 2017

Dear Minister

**Re: FSANZ's response to the presence of nano-hydroxyapatite in baby formula**

Recently Friends of the Earth commissioned testing of baby formula by Arizona State University, one of the world's leading labs for detecting nanomaterials.

They found that five of the seven samples contained nanoparticles. Three of the samples contained nano-hydroxyapatite, with two being in needle-like form.

Following similar testing done on baby formula brands in the United States, FSANZ indicated on its website that the use of nano-hydroxyapatite was not permitted in baby formula in Australia.<sup>i</sup>

When FSANZ learned of our test results the agency pulled that web page down and have replaced it with a page asserting the safety of nano-hydroxyapatite, effectively permitting the use of that material in baby formula.

Friends of the Earth has several serious concerns regarding this conduct.

A clear statement that nano-hydroxyapatite is prohibited in baby formula has simply been discarded by FSANZ in a unilateral regulatory change that does not adhere to the Food Regulation Ministerial Forum Guidelines nor the required processes for altering the Food Code. It breaches due process, including the right of the public to be involved in such decisions.

This unilateral step taken without additional data, studies or evidence. In our view it puts babies at risk and undermines the credibility and integrity of the agency.

We also believe that FSANZ has failed to adhere to the Food Regulation Ministerial Council's policy for ensuring the safety of infant formula. The policy recognises that children are particularly vulnerable:

*"because they have immature immune systems and organs...For some infants, infant formula products may be the sole or principal source of nutrition. For these reasons, there is a greater level of risk to be managed compared to other populations."<sup>ii</sup>*

As a result of this higher level of exposure and risk, the policy sets out pre-market safety assessment requirements that clearly capture the use of nanoparticles in baby formula:



*Pre-market assessment...should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. 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.<sup>iii</sup>*

Further, the Food Code explicitly prohibits the use of nutritive substances in baby formula unless they are expressly permitted. No nano forms of hydroxyapatite, calcite, or silica have been authorised for use in Australia.<sup>iv</sup>

The most comprehensive review of the safety data relating to nano-hydroxyapatite has been done by the European Unions Scientific Committee on Consumer Safety (SCCS).<sup>v</sup> The SCCS reviewed the use of nano-hydroxyapatite in oral cosmetics, particularly toothpaste and mouthwash. The SCCS recommended that the needle-like form of hydroxyapatite not be used in oral cosmetics because it is potentially toxic.

If it is potentially toxic in oral cosmetics it should certainly not be used in baby formula, where levels of exposure will be higher and baby formula may be the only food a baby is consuming.

The SCCS also concluded that there was insufficient data to reach a finding of safety regarding nano-hydroxyapatite. This directly contradicts the position FSANZ is taking in relation to these test results. In this context, it is critical to know that FSANZ has not conducted any formal review of nano-hydroxyapatite - nor has the agency sought or produced additional data.

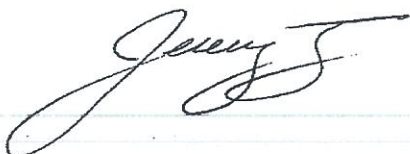
FSANZ is asserting the safety of nano-hydroxyapatite in spite of the evidence not because of it.

We are aware that they are basing their assertion of safety on data that indicates nano-hydroxyapatite dissolves in stomach acid.<sup>vi</sup> The FSANZ view appears to be that dissolution in the stomach makes the nanoparticles safe. There are several problems with this assertion. Firstly, as Professor Tom Faunce has pointed out,<sup>vii</sup> nano-hydroxyapatite may be absorbed through the mouth. Secondly, the dissolution in stomach acid may not be complete. In fact, the evidence for dissolution is based on *in vitro* studies, not *in vivo* analysis. The stomachs of babies have a higher pH than adults. For example, the pH in the stomach of newborns is often close to neutral – making it less likely that the nano-hydroxyapatite would dissolve. Finally, one of the few peer-reviewed studies looking at consumption of nano-hydroxyapatite has noted that even after dissolution, the needle-like form of nano-hydroxyapatite can reform.<sup>viii</sup> While the paper provides no details as to how and in what circumstances this occurs, these combined factors indicate that an assertion of safety based on dissolution is not justified.

Based on the Food Code, all products containing nanoparticles should be recalled immediately as they are not permitted. Secondly, we urge the Ministerial Forum to request that FSANZ immediately undertake testing of brands not tested by Arizona State University to ensure that they do not contain illegal nanoparticles.

The attached briefing note provides additional detail on the tests, test results and health concerns associated with nano-hydroxyapatite.

Yours Sincerely



Jeremy Tager

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<sup>i</sup> FSANZ (2016) Nanoparticles and infant formula, available at: <http://emergingtech.foe.org.au/wp-content/uploads/2017/06/FSANZ-website-statement-on-nano-hydroxyapatite-Oct-16-1.pdf>

<sup>ii</sup> Australia and New Zealand Food Regulation Ministerial Council, Food Regulation Standing Committee, Policy Guideline, Regulation of Infant Formula.

<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf>

<sup>iv</sup> Clause 2.9.1—5, Standard 2.9.1: Infant formula products, <https://www.legislation.gov.au/Details/F2017C00332>

<sup>v</sup> Scientific Committee on Consumer Safety (SCCS) (2016). Opinion on Hydroxyapatite (nano).

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_191.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf)

<sup>vi</sup> Schoepf, J. *et al.* (2017). Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. *Nanoimpact* 5:22-28

<sup>vii</sup> Han, E. (2017). Study finds 'potentially toxic' nanoparticles in Australian baby formula. *Sydney Morning Herald*.

[http://www.smh.com.au/business/consumer-affairs/study-finds-potentially-toxic-nanoparticles-in-australian-baby-formula-20170622-gwwb2j.html?promote\\_channel=edmail&mbnr=MTAyNTY1ODg&eid=email:nnn-13omn654-ret\\_news1-membereng:nnn-04%2F11%2F2013-news\\_am-dom-news-nnn-age-u&campaign\\_code=13INO010&et\\_bid=29084624&name=40\\_smh\\_newsalert&instance=2017-07-01--18-50--UTC](http://www.smh.com.au/business/consumer-affairs/study-finds-potentially-toxic-nanoparticles-in-australian-baby-formula-20170622-gwwb2j.html?promote_channel=edmail&mbnr=MTAyNTY1ODg&eid=email:nnn-13omn654-ret_news1-membereng:nnn-04%2F11%2F2013-news_am-dom-news-nnn-age-u&campaign_code=13INO010&et_bid=29084624&name=40_smh_newsalert&instance=2017-07-01--18-50--UTC)

<sup>viii</sup> Schoepf, J. *et al.* (2017). Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. *Nanoimpact* 5:22-28

