

Documents reveal FSANZ misled minister regarding nanoparticles in baby formula



In July 2017, independent testing commissioned by Friends of the Earth found nanoparticles in popular Australian infant formula products that are both illegal in Australia and potentially dangerous.¹

Documents released under Freedom of Information laws show that our food regulator Food Standards Australia New Zealand (FSANZ) unilaterally 'legalised'² the use of nano-hydroxyapatite (n-Ha) in baby formula after previously declaring it wasn't permitted³ FSANZ also misled its minister - Dr David Gillespie⁴, the Chinese Government⁵, and the public⁶, by stating that members of its Scientific Nanotechnology Advisory Group (SNAG) supported its claims that the ingredient was safe - when they actually raised safety concerns.

'Legalising' the presence of nano-hydroxyapatite

In changing its position on the legality of nano-hydroxyapatite, FSANZ had to take three extraordinary steps. Firstly, FSANZ abandoned its previously unequivocal position that nano-hydroxyapatite was not permitted in baby formula.⁷ Secondly, it accepted without evidence the industry position that the nano-hydroxyapatite was not intentionally added to baby formula.⁸ Finally, FSANZ concluded that its prohibition on nano-hydroxyapatite only applied if it was intentionally added.⁹

One FSANZ staff members questioned how the agency would manage the complete change of position on the legality of n-Ha.¹⁰ and the answer appears to be that FSANZ will simply pretend that no legal question ever arose.

The Chinese Government, in fact, asked specifically if the n-Ha in baby formula was legal. FSANZ didn't answer the question.¹¹

In its de facto legalisation of the use of nano-hydroxyapatite in baby formula FSANZ has failed to adhere to the Food Regulation Ministerial Council's policy for ensuring the safety of baby formula. This states that:

*"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."*¹²

Further, the Food Code prohibits the use of nutritive and novel substances in baby formula unless they are expressly permitted.¹³

Asserting safety

Despite the only comprehensive review of nano-hydroxyapatite finding that n-Ha is potentially toxic and there is insufficient data to say it is safe,¹⁴ FSANZ, without any additional data stated on its website that:

*"FSANZ has reviewed the available information and concluded it does not contain any new evidence to suggest these products pose a risk to infant health and safety. This conclusion is supported by experts from our Scientific Nanotechnology Advisory Group."*¹⁵

A SNAG member wrote to FSANZ challenging this assertion, saying that at the only meeting SNAG had had to that point, the safety of nano-hydroxyapatite hadn't even been discussed.¹⁶

Another SNAG member indicated she would be willing to support the statement if FSANZ provided the information that supports the finding of safety and dissolution in water.¹⁷ FSANZ provided no additional information.

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SNAG met subsequently and could not reach a consensus on the safety of n-Ha, or support FSANZ's claims that n-Ha fully dissolves in infant stomachs.¹⁸ At the request of SNAG, FSANZ changed the wording of the statement on its website to:

"FSANZ consulted with members of our Scientific Nanotechnology Advisory Group in reaching our conclusions."¹⁹

However, FSANZ failed to notify its minister of SNAG's actual views or to adjust the statement on its website asserting that n-Ha was safe.²⁰ FSANZ continued to assert that there was no evidence that n-Ha caused harm, despite a SNAG member pointing out that the Scientific Committee on Consumer Safety review of n-Ha was evidence of harm.²¹ FSANZ insisted the n-Ha was not intentionally added to the baby formula, while SNAG concluded they didn't know based on the available information.²² SNAG members also contested the claim that the n-Ha would simply dissolve in the stomach acid of children, pointing out that dissolution issues aren't simple and raising concerns that infants don't have acidic gut fluid.²³

Misleading its minister

In advice to its minister²⁴ FSANZ claimed SNAG supported its conclusion that there are no health concerns associated with n-Ha. The agency also asserted that n-Ha dissolves in the stomach into calcium and phosphate - both essential ingredients in baby formula - and intimated that it may even be good for infants.²⁵ None of these assertions are supported by SNAG but FSANZ never corrected the record with its own Minister.

In its Ministerial briefing²⁶ FSANZ also fails to mention the legal issues around n-Ha, including its new interpretation of the Food Code.

Institutional corruption

FSANZ has gone to disturbing lengths to avoid enforcing its own regulations and in doing so is putting infants at risk of exposure to a substance that has not been shown to be safe - and may in fact be toxic. It is only the infant formula industry that benefits from FSANZ's duplicity.

It is clear that there is a systemic problem with FSANZ. The agency is deeply compromised by its close relations with big food multinationals. It consistently refuses to regulate, ignores legitimate health concerns and won't act for the public good except in the most extreme cases. The agency needs to be fully investigated and overhauled.

1 FoE (2017) Illegal and potentially toxic nanoparticles found in baby formula, 2/7/17, <http://emergingtech.foe.org.au/illegal-and-potentially-toxic-nanoparticles-found-in-baby-formula/>

2 Document 20, June FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/Doc-20_Redacted.pdf; Document 21, June FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/Doc-21-Meeting-Notes-19-May-2017_Redacted.pdf; Document 17, July FOI, <http://emergingtech.foe.org.au/wp-content/uploads/2018/01/17-SNAG-mtg-31-May.pdf>; Document 80, July FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/80-RE_nano-particles-in-infant-formula.pdf

3 Screen grab of FSANZ's website, Oct 2016, <http://emergingtech.foe.org.au/wp-content/uploads/2017/06/FSANZ-website-statement-on-nano-hydroxyapatite-Oct-16-1.pdf>

4 Document 40A, July FOI, <http://emergingtech.foe.org.au/wp-content/uploads/2018/01/40A-MB17-002556-Nanoparticles-in-infant-formula.pdf>

5 Document 61, July FOI, <http://emergingtech.foe.org.au/wp-content/uploads/2018/01/61-RE-Follow-up-questions-Nanoparticles-in-IF-DLMFor-Official-Use-Only.pdf>

6 Screenshot of FSANZ's webpage 10/7/17, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/Nanoparticles-and-infant-formula-FSANZ-website-10_7_17.pdf

7 Ibid.

8 Document 21, June FOI; Document 17, July FOI; Document 40A, July FOI; Document 49, July FOI;

http://emergingtech.foe.org.au/wp-content/uploads/2018/01/49-FW_Proposed-SNAG-Teleconference-DLMFor-Official-Use-Only.pdf

9 Document 20, June FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/Doc-20_Redacted.pdf; Document 21, June FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/Doc-21-Meeting-Notes-19-May-2017_Redacted.pdf; Document 17, July FOI, <http://emergingtech.foe.org.au/wp-content/uploads/2018/01/17-SNAG-mtg-31-May.pdf>; Document 80, July FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/80-RE_nano-particles-in-infant-formula.pdf

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10 Document 20, June FOI

11 Document 61, July FOI

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

13 Food Standards Australia New Zealand, Australia New Zealand Food Code, Standards 2.9.1,

<https://www.legislation.gov.au/Details/F2017C00332>

14 Scientific Committee on Consumer Safety (SCCS) (2016). Opinion on Hydroxyapatite (nano). p. 18,

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf

15 Screen grab of FSANZ's website, 10/7/17,

<https://web.archive.org/web/20170710183910/http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/Nanoparticles-and-infant-formula.aspx>

16 Document 46, July FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/46-Re_-Proposed-SNAG-Teleconference-SECUNCLASSIFIED.pdf

17 Document 49, July FOI, http://emergingtech.foe.org.au/wp-content/uploads/2018/01/49-FW_-Proposed-SNAG-Teleconference-DLMFor-Official-Use-Only.pdf

18 Document 65, July FOI, <http://emergingtech.foe.org.au/wp-content/uploads/2018/01/65-SNAG-mtg-10-July.pdf>

19 Screen grab of FSANZ's website, 18/7/17,

<https://web.archive.org/web/20170719160510/http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/Nanoparticles-and-infant-formula.aspx>

20 FSANZ (2017) Nanoparticles and infant formula, July 2017,

<http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/Nanoparticles-and-infant-formula.aspx>

21 Document 65, July FOI

22 Document 21, June FOI; Documents 17, 65, July FOI.

23 Document 17, July FOI.

24 Document 40A, July FOI

25 *Ibid.*

26 *Ibid.*