

**From:** [Duffy Gillian](#)  
**To:** [REDACTED]  
**Subject:** FW: Nanoparticles in infant formula [SEC=UNCLASSIFIED]  
**Date:** Friday, 14 July 2017 1:46:00 PM  
**Attachments:** [image003.jpg](#)  
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[image006.png](#)  
[image007.png](#)

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Dear [REDACTED]

Thank you for your email regarding the evidence base for the Food Standards Australia New Zealand (FSANZ) guidance in response to the recent media on nanoparticles in infant formula. First I would like to re-iterate that Carers of infants should not be alarmed by this report or concerned about the safety of these products. I have then provided some information about our approach to regulation of nanotechnology and food and nanoparticles in infant formula.

#### **FSANZ approach on regulation of nanotechnology and food**

I note you attached the 2007 report from the United Kingdom Food Standards Agency which outlines some of the factors that should be considered in future evaluation of nanotechnologies in food regulation. I am not able to provide you with updates from the UK since this report was published.

However FSANZ has also been working with other Australian regulatory agencies since 2007 to ensure that the safety and suitability of any food products manufactured using nanotechnology can be determined. For information on FSANZ's approach you can see our webpage on Nanotechnology and Food <http://www.foodstandards.gov.au/consumer/foodtech/nanotech/Pages/default.aspx>

Food substances including food additives, processing aids, novel foods and nutritive substances that involve the use of nanotechnology require premarket approval if potentially unsafe. This approval requires a rigorous safety assessment by FSANZ using the best available scientific evidence. The requirements for a comprehensive scientific safety assessment is set out in FSANZ's [Application Handbook](#) which states that in cases where particle size is important to achieving the technological function, or may relate to a difference in toxicity, information must be provided on particle size, size distribution, and morphology, as well as any size-dependent properties.

FSANZ has not received any applications to approve any nanoscale particles for food use and is actively monitoring research and commercialisation developments relevant to food.

#### **Nanoparticles in infant formula**

FSANZ has not relied on one piece of research to come to our recent position on the recent media. We have reviewed the available information and consulted with a number of independent experts as well as with members of our [Scientific Nanotechnology Advisory Group](#) in reaching our conclusions.

Food is naturally composed of nanoscale sugars, amino acids, peptides and proteins, many of which form organised, functional nanostructures. For example, proteins are in the nanoscale size range and milk contains an emulsion of nanoscale fat droplets. Human milk also contains nanoscale fat droplets. Humans, including infants, have consumed these particles in foods throughout evolution without evidence of adverse health effects related to the materials' nanoscale size.

It is important to note that the presence of nano-size particles in food are usually not the result of intentional addition (e.g. as an additive), as some can occur naturally and others may be produced during processing. The presence of something, whether nanoscale or not, in a food that does not have a permission in the Code does not mean the food is unsafe.

Infant formula is based on milk, which naturally contains calcium and phosphorus (as calcium phosphates in different forms). As you are probably aware calcium and phosphorus are essential minerals and are required in infant formula. Several chemical forms of these two minerals are permitted additives to infant formula.

The form of calcium phosphate detected in the Australian infant formula samples – hydroxyapatite – is a naturally-occurring form of calcium phosphate that is a significant component of bone and teeth. It provides structure and strength to teeth and bone and provides a reservoir of calcium that helps maintain a constant concentration of calcium in the blood. It is widely used as a source of calcium in health supplements. Hydroxyapatite is soluble in acidic environments such as the stomach, so it can be reasoned that small amounts in food will likely dissolve and release its calcium.

There is currently no evidence to indicate that nano-dimensions of particulates in food are of themselves a risk to human health. Normal human breast milk is composed of a nanoscale materials (eg casein protein agglomerates and milk fat globules have nanostructure). FSANZ's conclusions that there are no public health implications for the finding of small crystals of naturally occurring calcium phosphates in milk-based products is consistent with a body of independent expert opinion.

Some references you may find helpful are listed below:

Gaucheron F. (2005) The minerals of milk *Reprod. Nutr. Dev.* 45; 473–483.

<https://hal.archives-ouvertes.fr/hal-00900570/document>

McGann TC, Buchheim W, Kearney RD, Richardson T. (1983) Composition and ultrastructure of calcium phosphate-citrate complexes in bovine milk systems. *Biochim Biophys Acta*. 1983 Nov 8;760(3):415-20.

Schoepf J Bi Y, Kidd J, Herckes P, Hristovski K, Westerhoff P (2017) Detection and dissolution of needle-like hydroxyapatite nanomaterials in infant formula. *NanoImpact* 5 22–28

Fletcher N and Ba holoemaeus A (2011) Regulation of Nanotechnologies in Food in Australia and New Zealand. *Int J Risk Analysis* Vol 1(2) pp.33-40.

[https://www.intechopen.com/books/international\\_food\\_risk\\_analysis\\_journal/regulation\\_of\\_nanotechnologies\\_in\\_food\\_in\\_australia\\_and\\_new\\_zealand](https://www.intechopen.com/books/international_food_risk_analysis_journal/regulation_of_nanotechnologies_in_food_in_australia_and_new_zealand)

Kind regards

Gillian

**Gillian Duffy**

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**From:** [REDACTED]  
**Sent:** Thursday, 6 July 2017 8:47 AM  
**To:** Media  
**Subject:** Nanoparticles in infant formula  
Dear FSANZ

Thank you for your recent guidance on nanoparticles in infant formula.

As I have a long term interest in all aspects of infant and young child feeding I would be grateful if you could send me the research evidence that led to your recent position as I noted that in 2016 FSANZ expressed some uncertainty about the safety of nanoparticles. The attached report from 2007 appears to indicate taking a precautionary principle stand is wise particularly where vulnerable infants are concerned and although I have searched for new studies that I expected would follow this report I have been unsuccessful.

I look forward to receiving the information. Web links to publications will be sufficient although any research papers you are able to share would be most welcome of course.

I apologise for sending this email to three separate departments of FSANZ but I could not find an email address purely for correspondence purposes. I trust you will forward my email to the appropriate person.

Thank you.


Yours sincerely

[REDACTED]

[REDACTED]

[REDACTED]  
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