Consultation with the Scientific Nanotechnology Advisory Group (SNAG) regarding on hydroxyapatite nanoparticles in infant formula

Teleconference #1 - 31 May 2017

Participants: Trevor Webb (Chair), Steve Crossley, Leise Berven, Gill Duffy, and Rosalind Dalefield (FSANZ); Nobheetha Jayasekara, Maxine McCall, and Brian Priestly (SNAG)

Purpose of the meeting: to seek feedback on the Friends of the Earth (FOTE)-commissioned study and comments on:

- Validity of the methods
- Data indicating whether particles were intentionally engineered

Conflicts of interests (CoI): The Chair requested SNAG members to declare any further CoI. All members confirmed that they had no further CoI. BP reported that he had been approached by the Australian Science Media Centre but did not provide comment to them.

Key Outcomes:

- SNAG members noted that the study showed that hydroxyapatite (HA) nanoparticles were present in the samples and the testing method was valid.
- SNAG members noted that study was not able to determine a quantitative proportion of HA nanoparticles in infant formula.
- SNAG members noted from the results presented, whether HA particles were intentionally engineered and added or not could not be determined. It was commented that the HA particles could occur naturally or through processing.
- Some members of SNAG noted that the presence of the particles did not represent a public health and safety risk since the particles were not bio-persistent; i.e. HA particles dissolve in the low pH of the stomach.
- However, the complexity around dissolution of HA nanoparticles in the gut and within the context of a food matrix was also noted.
- SNAG members advised that FSANZ should obtain also comments from Mike Roberts (member who was unavailable for this teleconference).

Teleconference #2 – 19 June 2017

Participants: Trevor Webb (Chair), Leise Berven, Nick Fletcher (FSANZ); Mike Roberts (SNAG)

Purpose of the meeting: to seek feedback on the FOTE-commissioned study and comments on:

- Validity of the methods
- Data indicating whether particles were intentionally engineered
- Health and safety implications

Conflicts of interests (CoI): No additional CoI were declared by Professor Roberts.

Key Outcomes:

- MR noted that the study showed that nanoparticles were present in the samples of infant formula but the methods were not quantitative.
- MR noted HA particles were likely to dissolve in the stomach to calcium and phosphate (essential nutrients).

- MR noted there was science to support the possibility that HA particles are naturally occurring from milk processing or from the calcium source.
- MR noted the images showing HA nano-needles were in an aggregated or agglomerated form (not individual particles) in aqueous solution. This would probably have implications for their absorbability in the gut particularly in food matrix. HA nano-needles are rare and form in specialised conditions.
- MR noted that supersaturated milk solutions (i.e. as a result of milk dehydration to form milk powder) could give rise to HA nano-needles.
- MR noted that the FOTE-commissioned study does not demonstrate that the HA particles pose a risk to infant health and safety.

Teleconference #3 – 10 July 2017

Participants: Trevor Webb (Chair), Leise Berven, Nick Fletcher; Gill Duffy (FSANZ); Nobheetha Jayasekara, Maxine McCall, and Brian Priestly, Simon Loveday, and Jan Herrmann (SNAG)

Purpose of the meeting:

- To seek further feedback FOTE-commissioned study
- To ask SNAG about how FSANZ should present its conclusions when referring to consultation with the SNAG
- To identify process for presenting conclusions of SNAG consultation in public fora

Conflicts of interests (CoI): No additional CoI were declared. MM reported that she had been approached by the FOTE but did not provide comment to them.

Key Outcomes:

- SNAG members noted the study did not provide evidence that the HA nanoparticles detected were intentionally added or engineered**.**
- SNAG members noted that the question of whether the presence of HA nanoparticles posed a risk to infant health and safety was not specifically asked in the first teleconference.
- Some SNAG members noted that evidence presented in the study was insufficient to show that the particles would dissolve in the infant gut and, therefore, it could not be determined whether the particles posed a safety risk.
- Some SNAG members noted that the nano-HA did not pose a risk to infant health due to their likely dissolution in the stomach.
- One SNAG member noted the conclusion of the 2016 EC Scientific Committee on Consumer Safety (SCCS) report on use of hydroxyapatite in oral cosmetic products: “The available information indicates that nano-hydroxyapatite in needle-shaped form is of concern in relation to potential toxicity.” Based on this report, the SNAG member considered that there is insufficient evidence to draw a conclusion of safety.
- FSANZ apologised for not adequately informing SNAG members of how their advice would be used and how this would be publically notified.
- FSANZ and SNAG members agreed to revise the website information to read: “FSANZ has consulted with members of the SNAG in reaching our conclusions”.
- FSANZ indicated it will review the process for reporting on the SNAG advice and ensure that we seek agreement by the SNAG when reflecting their advice on the FSANZ webpage.
- FSANZ noted that SNAG advice was one input into our assessment. Other inputs were our internal scientific expertise, review of the scientific literature, and the advice of other independent scientific experts.