Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2016 – 2017, 19 October 2016

Ref No: SQ16-000562

OUTCOME: 2 – Health Access and Support Services

Topic: Nanomaterials in Food

Type of Question: Written Question on Notice

Senator: Rice, Janet

Question:

In a document released under FOI in July 2016, FSANZ notes its view (to a manufacturer) that nanoparticles that dissolve in the water or lipid phases of the food to which they are added or in the gastrointestinal tract will not be considered nanoparticles for purposes of regulation.

Is it correct that this new view of what constitutes a nanoparticle for purposes of regulation under novel food provisions is proposed for the first time in Proposal P1024?

a) Is it correct that P1024 is merely a proposal at this point?

b) P1024 indicates that "Particulate, nanoscale materials that are new to the food supply will be subject to toxicological evaluation as outlined in the Application Handbook." Does this mean that nanoscale materials of materials previously approved will be required to apply for approval?

c) Based on this FOI document it appears that FSANZ is using this as the current definition of a nanoparticle for purposes of the novel food provisions– is that correct?

d) If yes, is there any legal basis for using this proposed definition?

e) Has this definition been subject to any Parliamentary oversight?

f) His this definition been agreed by the Australia and New Zealand Ministerial Forum on Food Regulation?

g) What peer reviewed science is FSANZ relying upon in proposing this definition?

h) Is it the view of FSANZ that nano titanium dioxide meets this definition of a nanoparticle in food?

i) Is it the view of FSANZ that nano silica meets this definition of a nanoparticle in food?

j) Is it the view of FSANZ that nano silver meets this definition of a nanoparticle in food?

k) If no to g), h) or i) please identify the peer reviewed studies that demonstrate the nanoparticles dissolve in water or lipids or in the gastronintestinal tract.

Answer:

The FSANZ *Application Handbook* prescribes requirements for particle size, size distribution and morphology as well as any size dependent properties to be included in applications for the approval of processing aids, food additives, nutritive substances and novel foods, and for variations of maximum levels of chemical contaminants or natural toxicants. The principles introduced by Proposal P1024 are intended to separate nanoscale materials according to their solubility in water or oil into two categories of assessment only. Those that are soluble would be subject to a conventional chemical risk assessment process. Materials that are insoluble would be subject to a full toxicological assessment that also considers the implications of any potential novel physicochemical properties that may be associated with the particulate nature of the material.

a) Yes, P1024 is a proposal developed to investigate improvements to the Code's regulation of nutritive substances and novel foods.

b) This would be the case if previously approved materials were altered to be produced in the nanoscale and the particle size influences the toxicity of the material.

c) No.

d) to k)
Not applicable. See answer to parts a) and c).