

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 – 2018, 29 & 30 May 2017

Ref No: SQ17-000754

OUTCOME: 2 – Health Access and Support Services

Topic: P1024 and Nanomaterials

Type of Question: Written Question on Notice

Senator: Janet Rice

Question:

The following questions are following up on FSANZ responses to SQ16-000562. In responding to the first part of the question you note that P1024 proposes different levels of assessment for different types of nanoscale particles depending on solubility.

- a) FSANZ indicates that a previously approved nanomaterial will only be required to be assessed under the new proposed rules if the materials were “altered to be produced in the nanoscale and the particle size influences the toxicity of the material.”
 - i) What level of evidence does/would FSANZ require to demonstrate that particle size “influences the toxicity of the material”?
 - ii) Does “altered to be produced in the nanoscale” mean intentionally produced?
 - iii) If yes to (ii), what criteria are used to determine intent?
- b) Is the extent of solubility the only criteria for determining if a full toxicological assessment of a nanomaterial is necessary?

Answer:

- a)
 - i) Food Standards Australia New Zealand (FSANZ) provides guidance to applicants through the *Application Handbook*. The *Application Handbook* sets out data requirements but does not describe the “level of evidence” required to make a regulatory decision. This is made on a case-by-case basis using a weight of evidence approach to ensure protection of public health and safety. This applies equally to nanoscale and conventional materials.
 - ii) No.
 - iii) Not applicable.
- b) No. 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 an assessment that also considers the implications of any potential novel physicochemical properties that may be associated with the particulate nature of the material.