

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2015 - 16, 21 October 2015

Ref No: SQ15-000825

OUTCOME: 1 - Population Health

Topic: Safety of Silica and Titanium Dioxide

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

FSANZ has stated that it “is not aware of any information that suggests different particle sizes of titanium dioxide” may be more likely to produce adverse health effects. In one IARC monograph on titanium dioxide, the authors note that “nanoscale TiO₂ elicited a significantly greater increase in chemokines (associated with pulmonary emphysema and alveolar epithelial cell apoptosis) than did the microscale TiO₂.” Another IARC monograph from 2010 on TiO₂ noted that “In-vitro studies with fine and ultrafine titanium dioxide and purified DNA show induction of DNA damage that is suggestive of the generation of reactive oxygen species by both particle types. This effect is stronger for ultrafine than for fine titanium dioxide.”

- a) In light of conclusions such as these and the growing body of peer reviewed literature indicating various potential health concerns with nano forms of silica and titanium dioxide, would FSANZ agree that this is evidence that nano sized particles behave differently than those at conventional scale and this may result in health impacts?
- b) Is FSANZ aware that in 2006, the IARC (of the WHO) declared titanium dioxide a possible carcinogen as a result of inhalation? In 2010, the IARC indicated that determining the carcinogenicity of nano TiO₂ through other exposure pathways – including oral ingestion – was a priority?
- c) Is FSANZ aware that both nano titanium dioxide and nano silica are being reviewed by the EU Chemical Agency (ECHA) because of concerns regarding impacts on human health from exposure to these nano chemicals?
- d) And is FSANZ aware of the growing number of peer reviewed studies showing impacts in animal and in vitro studies – including on cells and DNA - as a result of the ingestion of these nanoparticles?
- e) Is FSANZ familiar with the recent review by the European Commission’s Scientific Committee on Consumer Safety of 4 kinds of nano silica used in cosmetics that was unable to make a finding of safety because the data was so inadequate?

- f) Would you agree that these studies, reviews and findings suggest that both nano silica and nano titanium dioxide “may present safety concerns” such that a manufacturer should be submitting any product containing nano titanium dioxide or nano silica to FSANZ for pre-market safety assessment and approval?

Answer:

- a) The cited information does not relate to the toxicity of titanium dioxide in food (i.e. exposure via oral ingestion) and does not alter Food Standards Australia New Zealand’s (FSANZ’s) conclusions.
- b) FSANZ is aware of the IARC report from 2006. However, the IARC classification based on the inhalation exposure route is not relevant to a consideration of the risks associated with titanium dioxide in foods. The same report notes that titanium dioxide did not cause an increase in any tumour type in carcinogenicity studies in laboratory animals when administered in the feed. There is also no evidence in the report to suggest that titanium dioxide is carcinogenic in humans when ingested in foods.
- c) FSANZ is continuing to monitor the developing scientific literature on nanoscale materials and is aware that the European Chemicals Agency is seeking to review data on titanium dioxide and silicon dioxide.
- d) FSANZ is continuing to monitor the developing scientific literature on nanoscale materials, including animal and in vitro studies.
- e) FSANZ is aware of the European Commission’s Scientific Committee on Consumer Safety (SCCS) report on silica, hydrated Silica, silica silylate and silica dimethyl silylate for use in leave-on and rinse-off cosmetics products. The report is of limited use for food risk assessment because the silicon dioxide that can be used in food is not the same as the different synthetic amorphous silica types (ie surface coated) to which the conclusions of the SCCS report apply.
- f) No. Standards 1.3.1 – Food Additives and 1.3.4 – Identity and Purity in the *Australia New Zealand Food Standards Code* permit the use of food grade titanium dioxide and silicon dioxide as food additives in food subject to specified conditions.