

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017–2018, 29 & 30 May 2017

Ref No: SQ17-000733

OUTCOME: 2 – Health Access and Support Services

Topic: Nanomaterials in food

Type of Question: Written Question on Notice

Senator: Janet Rice

Question:

FSANZ has noted that “Titanium dioxide has long been known to contain nanoparticles and these will have been present in the material used in the toxicity tests that supported approval of titanium dioxide as a food additive.”

- (a) Were the toxicity tests that supported approval of titanium dioxide different from the ingestion studies identified by ToxConsult?
 - (i) If yes to a) how many toxicity tests were conducted?
 - (ii) When were the studies conducted?
 - (iii) Who conducted the studies?
 - (iv) Have the studies been subject to peer review?
 - (v) Did these toxicity tests suffer from any defects or limitations that limit their relevance or utility?
 - (vi) What is the basis for concluding that the titanium dioxide used in those tests contained nanoparticles?
 - (vii) If these tests aren't public, please table them.
- (b) How long has titanium dioxide been known to contain nanoparticles?
- (c) Has the size, nature or average percentage of nanoparticles in food grade titanium dioxide changed over the decades in which it has been in use?
- (d) If yes to c) please describe the changes and the evidence that supports FSANZ's response.
- (e) Has FSANZ assessed the quality of the 3 published ingestion studies identified by ToxConsult?
 - (i) Are there any problems, limitations or defects in those 3 studies?
- (f) Is FSANZ's decision not to take any further steps following from this study based on these three studies?
 - (i) If no, what additional data was used by FSANZ to arrive at its position?
 - (ii) In this context of such a limited number of dated studies, why does FSANZ think that previously unseen results, such as those found in the January 2017 study, do not warrant further investigation?

Answer:

- (a) No. The approval of titanium dioxide as a food additive is based on the assessment published by Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1969. The ToxConsult Pty Ltd report references the original JECFA report.

However, EFSA (2016) and the ToxConsult review commissioned by FSANZ (2016) are both more recent evaluations of the safety of titanium dioxide. On the basis of more recent research, both 2016 evaluations concluded that the evidence did not support claims of significant health risks for food grade titanium dioxide.

- (i) – (vii) Not applicable.
- (b) Titanium dioxide has always existed in nature in several crystalline forms and may contain particles in the nano-and micro-range. The amount of nanoscale particles measured in food grade titanium dioxide has been dependent on the method used to measure particle size. There is no standardised method.
- (c) FSANZ is not aware of evidence to indicate that the size, nature or average percentage of nanoparticles in food grade titanium dioxide changed over the decades in which it has been in use.
- (d) Not applicable.
- (e) No. FSANZ commissioned the ToxConsult review in order to obtain an expert independent opinion on the studies on safety of titanium dioxide. FSANZ is aware of the studies cited in the ToxConsult report.
- (i) Assuming the question is in reference to the two ingestion studies by Bockmann et al (2009) and Jones et al (2015), the ToxConsult report cites limitations relating to influences on absorption that are unrelated to particle size, characterisation of the administered dose of titanium dioxide and lack of experimental details provided in Bockmann (2009).
- (f) No (assuming this question relates to the 2017 French study).
- (i) The decision is based on the weight of evidence from available studies in animals and humans including those referenced in considerations of overseas regulatory agencies and bodies, and the long history of safe use of titanium dioxide as a food additive worldwide.
- (ii) The January 2017 study provided preliminary evidence with limitations that restricts its relevance to humans (see SQ17-000733). FSANZ continues to monitor the research around the potential applications of nanotechnologies to foods. If FSANZ was to become aware of further research indicating public health issues with nano-titanium dioxide in food, then FSANZ would work with state and territory enforcement agencies to develop appropriate risk management measures.