Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2015 - 16, 21 October 2015

Ref No: SQ15-000778

OUTCOME: 1 - Population Health

Topic: Safety of Nanoparticles

Type of Question: Written Question on Notice

Senator: Madigan, John

Question:

On three occasions in Estimates questions on notice, FSANZ has been asked whether it believes nanomaterials being used in food are safe. On two occasions you failed to answer, simply noting that you are 'not aware' of any nanomaterials being unsafe for human consumption. The third time you were asked you indicated that information about foods that are potentially unsafe should be directed to the relevant state agency (SQ14-001345).

1. Would FSANZ agree its answer to the question at Estimates on 21 October 2015 that there is no evidence to suggest that nano silica is not safe is very different from saying that nano silica is safe for human consumption?

2. Is it the view of FSANZ that the intentional use of nano titanium dioxide in food products is safe?

3. In your reply to a recent story in the Sydney Morning Herald you comment online that FSANZ has "not identified any health effect known to be associated with the use of nanoparticles of titanium dioxide and silica, following oral ingestion in foods". Could you clarify if this refers solely to health effects in studies looking at human health impacts associated with oral ingestion by humans of nanoparticles of silica or TiO2 in food? (as opposed to animal or in vitro studies)?

4. Would you agree that 'not identifying any health effect' is entirely different from a conclusion of safety?

5. What studies or data is FSANZ aware of that suggests or demonstrates that oral ingestion of nanoparticles of titanium dioxide or silica in food is safe? Could these be tabled please?

6. Is there, in FSANZ's view, sufficient data to make a finding that the consumption of intentionally produced nano silica and nano titanium dioxide in food are safe?

7. If yes, what studies are these conclusions based on?

8. In circumstances where there is inadequate data to make a finding of safety in relation to the use of nanoparticles in food, what are manufacturers expected to do – should they apply for pre-market testing and approval or just go ahead and commercialise?

9. For any of the 14 products containing nanoparticles found on Australian shelves, have the manufacturers established the safety of the products that are now being sold?

10. Have you contacted these manufacturers in order to review or asked to review the data upon which they are relying in putting these products on the market in Australia?

11. Do you plan to?

Answer:

1. No. Food Standards Australia New Zealand (FSANZ) considers that food grade silicon dioxide is safe for human consumption in food when used according to permissions in Standard 1.3.1 – Food Additives and Standard 1.3.4 – Identity and Purity in the *Australia New Zealand Food Standards Code* (the Code). Food-grade silicon dioxide is also approved for use in food by the European Union, by the United States Food and Drug Administration (USFDA) and Codex Alimentarius of the Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO).

   Food-grade silicon dioxide has been evaluated and considered to be safe by the FAO/WHO Joint Expert Committee for Food Additives (JECFA). It has been used safely in foods for decades as a food additive. It is important to note that food-grade silicon dioxide will contain a proportion of particles in the nanoscale range due to its mode of production.

   New or novel forms of silicon dioxide that do not comply with established specifications, or are produced to perform a new technological function in the food, would require pre-market safety assessment by FSANZ.

2. FSANZ considers that titanium dioxide is safe for human consumption if used in accordance with permissions stated in Standards 1.3.1 and 1.3.4. Titanium dioxide is approved for use in food by the European Union, by the US FDA and by the Codex Alimentarius of the FAO/WHO. Titanium dioxide has also been evaluated by the JECFA and more recently by the European Food Safety Authority. It has an extensive history of safe use in human populations.

3. This is based on a lack of identified human health impacts associated with long established use of food-grade titanium dioxide and silicon dioxide. It is also supported by a weight of evidence in laboratory animal studies (see Attachment 1).

4. No, see answer to Question 1.

5. The attached list of publicly available studies suggests or demonstrates that oral ingestion of food-grade titanium dioxide or silicon dioxide do not present health and safety concerns.

6. FSANZ considers that food-grade titanium dioxide and silicon dioxide are safe for human consumption when used according to permissions in Standards 1.3.1 and Standard 1.3.4.

Food additives, processing aids, novel food substances, vitamins and minerals and nutritive substances added to food in accordance with the Code must meet appropriate specifications for identity and purity. These specifications are consistent with those used by the international community. If a new material does not conform to the specifications in Standard1.3.4, the manufacturer is required to make an application to FSANZ.

7. The evaluation by the FAO/WHO Joint Expert Committee for Food Additives of the safety of food grade titanium dioxide and silicon dioxide. In addition, there is an extensive history of safe use for both food additives. This information is provided in the literature review at Attachment 1.

8. Australian food laws prohibit the sale in Australia of food that is unsafe or unsuitable. These laws also prohibit the sale of food which does not comply with a requirement of the Code.

9. Australian food laws prohibit the sale in Australia of food that is unsafe or unsuitable, or which does not comply with a requirement of the Code.

10. See answer to Question 9.

11. No.

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