FSANZ misleads the public on the risks of nano-ingredients in food

In 2014 and 2015 our food regulator Food Standards Australia New Zealand (FSANZ) commissioned an expert toxicologist to prepare two reports on the use of nanotechnologies in existing food additives and food packaging. These reports were supposed to have been completed by March and June 2015 respectively. On 27th May 2016 Friends of the Earth submitted an FOI request to FSANZ for these reports and associated documents. Six days later FSANZ released the final reports - claiming that the reports concluded that **"**none of the nanotechnologies described are of health concern."[1]

FSANZ also states that "the consultant reviewed the evidence on nanoscale silicon dioxide, titanium dioxide and silver in food and found the weight of evidence does not support claims of significant health risks for food grade materials."[2] Friends of the Earth believe this is a deliberate misrepresentation of the reports. In fact, the reports draw attention to the major data gaps regarding the safety of nanoparticles (NPs) in food pointing out that "most of the research on the oral safety of NPs conducted to date has been acute or short term exposure toxicity rather than chronic exposure and morbidity."[3]

In the case of nano-silver (Ag) the report looking at the use of nano-ingredients in food concludes "there is currently insufficient data to confidently determine if Ag-NPs in food may present a toxicological hazard to humans at the dietary exposure levels so far estimated. Apart from there being no chronic studies, the finding that Ag after gavage administration of Ag-NPs has a longer residence time in the brain than other tissues warrants precaution when undertaking risk assessments…Similarly, research investigations with Ag-NPs showing potential for sperm abnormalities and delay of puberty onset need consideration." In the case of nano titanium dioxide (TiO_2) the report states that "overall this review concludes there is insufficient, directly relevant information available to confidently support a contemporary risk assessment of nano-TiO_2 in food."[4]

FSANZ is failing us

FSANZ is fundamentally failing in its role of ensuring that our food is safe to eat. Rather than following the precautionary principle and requiring safety testing before novel and potentially harmful ingredients are allowed in our food, FSANZ continues to justify its failure to do nothing. Absence of evidence of harm is not evidence of absence of harm yet huge data gaps exist that FSANZ should require to be filled before nanomaterials are used in food and food packaging! Urgent action is needed to ensure that the agency puts our safety and right to know what's in our food first and foremost.

So what else do the reports say?

The Food Report[5]

General conclusions

The report states that:

> *"Card et al. (2011) found 11,172 titles in their literature searches, however only 30 primary research articles (0.27%) were identified that contained information relevant*

> *to the oral safety of potential use of nanomaterials in food or the food industry...Due to the limited number of studies and the lack of complete characterisation of the nanomaterials studied, the authors concluded it was not possible to derive any overall conclusions regarding the toxicity of nanomaterials for food use…The authors concluded their evaluation indicated there was insufficient reliable data to allow clear assessment of the safety of oral exposure to food-related nanomaterials."*[6]

The report goes on to look at the toxicity data regarding nano-silica (SiO_2), titanium dioxide (TiO_2) and silver in more detail.

Nano-silica

The report states that "some types of nano-SiO_2 can cause chromosomal damage to mammalian cells in *in vitro* [cell culture] test systems" but that no data is available to see if the same effect occurs in humans and animals.[7]

One cited study found nanoparticles in the liver and kidney after rats were force fed nano-silica (Lee *et al.* 2014b).[8] In another study silicon accumulated in the spleen and an "increased incidence of hepatic fibrosis in the liver" was observed (van der Zande et al. 2014).[9] Another study - which found similar effects - noted that nano silica was more toxic than micron sized particles (So et al. 2008, as described in Dekkers et al. 2011, 2012).[10]

The report states that the uptake of silicon from nano-silica is likely to be about 0.2% of dietary exposure[11] and that "some tissue accumulation of Si from nano-SiO_2 is anticipated after oral exposure as it is expected to be ingested daily in food (Dekkers *et al.* 2012, van Kesteren *et al.* 2014)."[12]

The report refers to a study by Dutch Government scientists. This modelled the maximum (i.e. worst case) steady state concentration of silicon (Si) in the human liver. The study assumed 0.1% gastrointestinal absorption in humans, and used the estimated Dutch consumer intake of SiO_2 from Dekkers et al. (2011). Given that the projected concentration of Si in human liver was similar to the measured concentration in rats at which liver fibrosis was observed van Kesteren *et al.* (2014) concluded that synthetic amorphous silica in food may pose a health risk. However, they noted due to the uncertainties and assumptions in the risk assessment, it was not possible to draw firm conclusions."13

Somewhat surprisingly, the report reaches the conclusion that "from a hazard aspect that there is no evidence to suggest at human dietary exposures an unacceptable risk is likely. The database is however lacking in *in vivo* genotoxicity and developmental studies."[14]

Nano TiO_2

The report states that "overall this review concludes there is insufficient, directly relevant information available to confidently support a contemporary risk assessment of nano-TiO_2 in food."[15]

The authors note that "there are few studies investigating the toxicity of TiO_2 by dietary exposure, those that exist are old and do not specify the grade or particle size of the TiO_2. Nevertheless, these studies have been used by regulatory bodies to conclude that even at very high dietary levels (e.g. 100,000 ppm in diet) TiO_2 has very low toxicity to rats and mice when they are exposed in the diet for long periods."[16]

The authors also note that "despite TiO_2 being used as a food additive for many years there are no epidemiology studies available regarding possible associations with adverse health outcomes."[17] The authors further note that "data are not available on the absorption, distribution, elimination and toxicology of nano-TiO_2 when mixed with food."[18]

The authors not that "the weight of evidence indicates that oral exposure to nano-TiO_2, at least by gavage, can result in small increases in tissue titanium and is potentially associated with a range of tissue effects."[19] They observe that "the liver, spleen and kidney are the primary target organs. But dose- and time-dependent toxicity has been observed in other organs, e.g. the heart, thyroid, ovary and brain. Brain and behavioural effects were observed in off-spring after treatment of dams but traditional developmental studies with nano-TiO_2 were not located."[20]

The report refers to a study by Geraets *et al.* (2014) which concluded that "although there was limited uptake into the systemic circulation and tissues after ingestion, the very slow elimination from tissues might result in long term tissue accumulation and toxicity."[21]

Nano-silver

The report concludes that "there is currently insufficient data to confidently determine if Ag-NPs in food may present a toxicological hazard to humans at the dietary exposure levels so far estimated. Apart from there being no chronic studies, the finding that Ag after gavage administration of Ag-NPs has a longer residence time in the brain than other tissues warrants precaution when undertaking risk assessments…Similarly, research investigations with Ag-NPs showing potential for sperm abnormalities and delay of puberty onset need consideration."[22]

The report notes that "the European Food Safety Authority concluded in 2008 data were insufficient to assess the safety of a nanoAg hydrosol added to food supplements (EFSA 2008). The United States Environmental Protection Agency echoed this conclusion in 2010 in a broader sense for all uses of Ag-NPs, indicating additional long term studies with different particle sizes are still needed (US EPA 2010). Hadrup and Lam (2013) agreed that more data regarding different particle sizes is needed to draw a firm conclusion as to whether small NPs are more toxic than large ones following oral administration."[23]

The report notes that in a study where rats were force fed nano-silver "Ag concentrations in blood, faeces, urine (high dose only), and all tissues tested (liver, kidney, spleen, lung and brain) were increased compared with controls (Yun et al. 2015)."[24] The report notes that in one study "elimination of Ag occurred at a very slow rate from brain and testis, which still contained high concentrations 2 months after final exposures."[25]

Other studies report found that nano-silver caused brain damage (Skalska *et al*. 2014),[26] DNA damage (Kovvuru *et al.* 2014)[27], potential effects in liver, kidney and spleen,[28] and changes in gastrointestinal tissues and gut bacterial flora – with smaller silver nanoparticles having a greater anti-microbial effect.[29]

The food packaging report[30]

The report on the migration of nanoparticles into food from packaging makes it clear that FSANZ has made no effort to determine if nanomaterials in packaging are in use here. The report states merely that no one has applied to use nanomaterials in packaging. The fact

that they are known to be in use in the US and Europe suggests they will be here in imported foods. The authors state that the two most likely nanomaterials in packaging are nano clay and nano-silver (based on the numbers of patents found).The authors also note that - unlike Australia - EU, the US and Canada all have regulatory guidance relating to nanomaterials in packaging.

Data gaps

The report consistently draws attention to major data gaps noting that its "conclusions are tempered by the relatively few studies which have investigated the migration of nanoparticles *per se* from food packaging materials and the uncertainties in current analytical techniques for measuring possible migrated nanoparticles in foods/simulants"[31]

The authors observe that most of the migration studies that have been using food simulants – with very few looking at whole foods.[32] Furthermore, the complexities of assessing packaging matrices, different foods, different conditions (e.g. heat) and different time periods, makes the task difficult. The authors conclude that "migration of nanoparticles from food packaging material into food may be affected by multiple factors including temperature, time, concentration gradient, material properties, position of the nanoparticles in the packaging material, interaction between the nanoparticle and the material, and the nature of the food".[33]

Case by case safety assessments are needed

The authors note that "until such a time analytical techniques are more refined and more information is available, safety assessment of nanosilver-containing food packaging materials will be limited to conventional considerations of ionic silver release into foods… new food packaging products containing nanosilver migration experiments should be conducted on a case-by-case basis."[34]

Bacterial resistance

One major consideration missing from the report is the consideration of the role of antimicrobial products such as nano-silver in the spread of superbugs. Genes conferring antimicrobial resistance regularly travel quickly and widely due to the presence of mobile genetic (DNA) elements, such as plasmids, viruses, transposons and integrons. Resistance genes to silver have been found on a range of plasmids, notorious for containing multiple antibiotic resistance genes. This is why public health experts have called for a ban on the use of nano-silver in consumer products.[35]

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[1] FSANZ (2016) Reports on the use of nanotechnology in food additives and packaging, http://www.foodstandards.gov.au/consumer/foodtech/Pages/Reports-on-the-use-of-nanotechnology-in-food-additives-and-packaging-.aspx
[2] *Ibid.*
[3] Drew, R & Hagen, T. (2016) Potential Health Risks Associated with Nanotechnologies in Existing Food Additives, http://www.foodstandards.gov.au/publications/Documents/Safety%20of%20nanotechnology%20in%20food.pdf
[4] *Ibid.*, p. 8.
[5] *Ibid.*
[6] *Ibid.*, pp. 18-19.
[7] *Ibid.*, p. 5.
[8] *Ibid.*, p. 44
[9] *Ibid.*, p. 44, p. 51.
[10] *Ibid.*, p. 51.

[11] *Ibid.*, p. 44.
[12] *Ibid.*, p. 46.
[13] *Ibid.*, p. 40-41.
[14] *Ibid.*, p. 54
[15] *Ibid.*, p. 8.
[16] *Ibid.*, p. 7.
[17] *Ibid.*, p. 8.
[18] *Ibid.*, p. 7.
[19] *Ibid.*, p. 7.
[20] *Ibid.*, p. 38.
[21] *Ibid.*, p. 33.
[22] *Ibid.*, p. 9.
[23] *Ibid.*, p. 76.
[24] *Ibid.*, p. 60.
[25] *Ibid.*, p. 62
[26] *Ibid.*, p. 71
[27] *Ibid.*, p. 63.
[28] *Ibid.*, p. 77
[29] *Ibid.*, p. 64.
[30] Drew, R & Hagen, T. (2016) *Nanotechnologies in Food Packaging: an Exploratory Appraisal of Safety and Regulation*, http://www.foodstandards.gov.au/publications/Documents/Nanotech%20in%20food%20packaging.pdf
[31] *Ibid.*, p. 7.
[32] *Ibid.*, p. 21.
[33] *Ibid.*, pp. 18-19.
[34] *Ibid.*, p. 6.
[35] FoEA (2011) *Nano silver: policy failure puts public health at risk*, http://emergingtech.foe.org.au/wp-content/uploads/2011/10/Nano-silver_2011.pdf