**Postgrad symposium 2020 abstract**
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**Title:** Regulation in the face of uncertainty: how nanoparticles in the food chain challenge the status quo of risk assessment, risk management and regulatory frameworks

**Abstract:** Nanotechnology, as an enabling technology, has been hailed as the next 'industrial revolution'[1] and a 'key economic driver for the 21st century'[2]. Nanomaterials and nanoparticles have at least one dimension in the size range 1-100 nm and can be naturally occurring, incidentally produced or deliberately engineered. Incidentally produced and engineered nanomaterials and nanoparticles are commonly used in consumer products and equipment, medicines and medical devices, industrial applications, pesticides, and in the food and feed chain.

Relative to the bulk material, nanomaterials and nanoparticles have unique physico-chemical properties, including increased surface area, enhanced chemical reactivity and improved bioavailability. While these unique properties offer the basis for innovative design and application, they also confer potential hazards to human health. A wide variety of nanomaterials and nanoparticles exist and have received much industry, regulatory, academic and public attention. A significant example of this is titanium dioxide, which is primarily used as an additive in foods. Studies have demonstrated that 10-50% of the titanium dioxide added to some food products on the Australian market is present in nanoparticle form[3].

While no consensus among the scientific community as to the potentially hazardous nature of nanoparticles exists, there is a growing body of evidence around certain nanoparticles which indicates potential toxicity. Preliminary *in vitro* toxicity studies show that food-grade titanium dioxide nanoparticles can generate intracellular superoxide and alter epigenetic modifiers in human lung cells[4] and can induce anxiety and adenoma in colon and goblet cells[5]. In Australia, the use of titanium dioxide as a food additive is regulated by legislation enforced by Federal Government agency Food Standards Australia New Zealand (FSANZ). The question as to what precautionary actions FSANZ could and/or should take to mitigate or prevent the risks that may or may not eventuate from the potentially toxic presence of certain nanoparticles in foods is an important one and can be extended to other nanoparticles and other regulatory settings around the world. At the heart of this question is another more fundamental question: how do societies govern and regulate in the face of scientific uncertainty?

In this project, a review of historical and current regulatory approaches to nanomaterials and nanoparticles was conducted which considered Australian and international government, intergovernmental, and supranational responses. The review was conducted from two separate perspectives within a social and public health context: 1) a scientific perspective that reviewed the adequacy of existing legislation to protect consumers from potential public health risks that may arise in the future; and 2) a regulatory theory perspective that reviewed the legislative status quo for regulating in the face of scientific uncertainty, and how this has and/or should be applied to nanomaterials and nanoparticles.

From this review, six key regulatory considerations were identified as being present but currently under (or not) utilised adequately in risk assessment, risk management and regulatory frameworks around the world. The considerations range from 'soft law' approaches such as labelling, to 'hard law' approaches such as legislative reform. A case study on titanium dioxide nanoparticles in foods is used throughout the review to provide specific examples of the application of the regulatory considerations discussed. Finally, in this work, recommendations for, and reflections on the practicality of, implementing or bolstering these regulatory considerations in relation to nanomaterials and nanoparticles is provided for the Australian context.

[1] Teresko. (2003). Get Ready for the Age of Nanotechnology. *Forbes.com*.

[2] Bowman and Hodge. (2007). Nanotechnology and Public Interest Dialogue: Some International Observations. *Bulletin of Science, Technology & Society* 27(2), 118-132.

[3] Reed, Schoepf, Masles, Westerhoff. (2015). Detecting Engineered Nanomaterials in Processed Foods From Australia. *Friends of the Earth, Australia.*

[4] Jayaram and Payne. (2020). Food-Grade $TiO_2$ Particles Generate Intracellular Superoxide and Alter Epigenetic Modifiers in Human Lung Cells. *Chem. Res. Toxicol.,* https://dx.doi.org/10.1021/acs.chemrestox.0c00331.

[5] Medina-Reyes et al. (2020). Food-grade titanium dioxide (E171) induces anxiety, adenomas in colon and goblet cells hyperplasia in a regular diet model and microvesicular steatosis in a high fat diet model. *Food and Chem. Toxicol.* 146, 111786.