

# Nano-Based Food and Substantial Equivalence: A Category-Mistake

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## ABSTRACT

*In recent years regulators have become sensitized to the fact that advances in nanotechnology challenge current regulatory approaches and capacities. Since many of these issues parallel earlier debates on genetically modified foods, it seems highly likely that similar decision-making tools and approaches will be used for governing nano-based food. A key decision-making tool used by regulators in North America and Europe involves application of the principle of substantial equivalence. In this paper, the authors argue that substantial equivalence is an inapt arbiter of equivalence for nano-based food, and that it incorporates a fundamental flaw in logic known as a category-mistake.*

*Key words: Nanotechnology, Nano-Based Food, Substantial Equivalence, Regulation, Governance, Category-Mistake*

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## INTRODUCTION

Discoveries in nanoscience and advances in nanotechnology are revolutionizing science and industry, and are making advances in biotechnology pale by comparison (Mehta, 2002). Due to the rapid convergence of biotechnology and nanotechnology in the domain of food science in particular (Sozer & Kokini, 2009), regulators are increasingly challenged to develop robust and defensible approaches, tools, and frameworks for governing new technologies, and for minimizing the risks associated with novel foods that might have toxicological properties difficult to characterize (Xu et al., 2010),

changes in nutritional composition (Srinivas et al., 2010), or the development of new or altered human allergens (van Putten et al., 2010; Rubial-Mendieta et al., 1997). Collectively, these considerations represent the three main characteristics embedded into a regulatory approach that utilizes a decision-making principle known as substantial equivalence.

## SUBSTANTIAL EQUIVALENCE

The principle of substantial equivalence first emerged in the 1990s when regulators were given the task of assessing the safety of genetically modified foods in a policy environment where specific biotechnology regulations and

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dedicated hazard and risk assessment tools had not yet been developed. This policy vacuum was quickly filled with competing ideas on how best to regulate products of biotechnology. At that time a choice existed for treating genetically modified foods similarly to other functional innovations such as novel chemical compounds including pesticides, food additives and pharmaceuticals (Millstone, Brunner & Mayer, 1999). Moreover, evidence-based research could have been developed and deployed to establish acceptable daily intakes (ADIs). Due to a general reluctance on the part of industry to carry out toxicological studies, and also because the very notion of establishing ADIs for genetically modified food implied restricting or limiting consumption, substantial equivalence was eventually adopted and embedded into policy statements of the Organization for Economic Cooperation and Development (OECD), United Nations Food and Agriculture Organization (FAO), and the World Health Organization (WHO).

Substantial equivalence is essentially a comparative approach. It is not a risk assessment but rather a hazard assessment tool for identifying possible problem areas (Kuiper et al., 2002). Hazard assessment involves identifying and controlling hazards, while risk assessment involves calculating the probability of a hazard generating adverse outcomes multiplied by the consequences associated with exposure. Consequently, risk assessment is part of a risk management approach, whereas hazard assessment is simply one of the input variables in the management of risk (Leiss, 2001). Since risk controversies - like those seen on the question of nuclear safety (Mehta, 2005) - involve contested concepts of risk acceptability, it should be no surprise to discover that public opposition to genetically modified food has focused on the criteria used for approving these products (Levidow, Murphy & Carr, 2007), and on labelling (Dannenberg, 2009). Clearly, several lessons need to be learned from this history when considering the likely trajectory that nanotechnology will follow as its introduction accelerates (Mehta, 2004; Frewer, 2010). Thus,

sensitivity to consumer values (Vendermoere et al., 2009), general ethical considerations (Hunt & Mehta, 2006), preferences (Cobb & Macoubrie, 2004), and risk-benefit perceptions must become more central (Siegrist, Stampfli, & Kastenholtz, 2009). Additionally, there are strong arguments asserting that nano-based products represent a special case for application of the precautionary principle as a form of precautionary risk management and regulation (Clift, 2006).

Underlying the principle of substantial equivalence is the assumption that a genetically modified food can be deemed substantially equivalent to its natural counterpart if it has the same set of metabolites and similar sequences of amino acids and amides (Baker et al., 2006), falls within a specified range for identified nutritional and anti-nutritional components (Novak and Haslberger, 2000), and if it does not introduce unanticipated human allergens (Martens, 2000). If it passes these three levels of analysis, the food in question is generally regarded as safe and no additional regulatory scrutiny is required. In Canada and the United States this determination excludes the "novel" or genetically modified food from a requirement to label it as well. At the moment, substantial equivalence is the only widely accepted approach for assessing genetically modified food. Sophisticated experiments continue to show that genetically modified foods are quite similar to - but not equivalent with - their natural counterparts (Catchpole et al., 2005), in spite of the fact that few standardized approaches or statistical techniques are available for comparing across studies or food products. Pusztai and Bardocz (2006) urged caution about nano-based food, and nano-particles in food, and recommended that future research concentrate on nutritional and toxicological testing protocols including functional analyses of the effects of nano-based food on metabolism, organ and tissue development, endocrine functions, and gut flora. That appropriate safety testing is not currently done, according to Pusztai and Bardocz (2006), brings into question the adequacy of regulatory systems and their over-reliance on substantial equivalence.

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