

Rationales for the Food and Agricultural Applications of Nanotechnology and Exposure Science Required for Its Regulation

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Abstract

According to White House science advisors, U.S. federal government budgetary, personal, infrastructural and policy support is necessary for research into the Environmental Health and Safety (EHS effects) of exposure to Engineered Nanoscale Materials (ENMs) to guarantee the responsible commercialization of ENMs in consumer and industrial products. Validated databases of exposure data from Life Cycle Assessments (LCA) of products with ENMs requires adequate support and the cooperation of product developers. This article summarizes some EHS exposure research accomplished in the absence of the product developer cooperation and adequate support. EHS research into food and agriculture applications of nanotechnology is used to exemplify several challenges in developing the validated LCA exposure data bases required for risk assessments and subsequent regulation of nanotechnology enabled products.

Key words: agro-nanotechnology, Engineered Nanoscale Materials (ENMs), Life Cycle Assessment (LCA), exposure routes

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Fundamentação para as Aplicações Alimentares e Agrícolas da Nanotecnologia e Exposição da Ciência Necessária para a sua Regulamentação

Resumo

De acordo com assessores científicos da Casa Branca, é necessário o apoio orçamentário, pessoal, infra-estrutural e de políticas públicas do governo dos Estados Unidos para realizar uma investigação sobre os efeitos para o Ambiente, a Saúde e a Segurança («efeitos ASS») da exposição aos Materiais Engendrados em Nanoescala (MENS) para garantir a comercialização responsável dos MENS para o consumidor e para a indústria. As bases de dados sobre a exposição obtidas a partir de Avaliações do Ciclo de Vida (ACV) dos produtos com MENS requerem apoio adequado e cooperação por parte dos desenvolvedores desses produtos. Este artigo resume algumas pesquisas de exposição realizadas sem a cooperação dos desenvolvedores dos produtos e sem o apoio adequado. A pesquisa dos efeitos ASS nas aplicações de nanotecnologia em alimentos e na agricultura é usada para exemplificar os vários desafios para o desenvolvimento de bases de dados válidas sobre a exposição obtidas a partir de ACVs, necessárias para as avaliações dos riscos e a subsequente regulação de produtos que utilizam nanotecnologia.

Palavras-chave: agronanotecnologia, Materiais Engendrados em Nanoescala (MENS), Avaliações do Ciclo de Vida (ACV), rotas de exposição

Overview

The objective of the following presentation is to show how U.S. federal government supports the exposure science, with the mandated cooperation of commercialization applicants for products with nanotechnology, which could result in an effective regulation of nanotechnologies and Engineered Nanoscale Materials (ENMs). This process may be replicable, with variations, in other jurisdictions. I illustrate the difficulties of developing adequate scientific data about human, animal and environmental exposures to ENMs, using examples as food and agricultural applications of nanotechnology.

Protecting the State's investment in nanotechnology

The history of U.S. government leadership and investment in nanotechnology is a major example of research and risk-taking development that the for-profit sector avoids (Mazzucuto, 2014). A decade of U.S. government research and lobbying preceded the launching of the National Nanotechnology Initiative (NNI) in 2001. As in 2015, the 26 NNI coordinated agency budgets amount to more than \$22 billion in U.S. federal investment in nanotechnology projects and grant-making since 2001 (NATIONAL NANOTECHNOLOGY INSTITUTE BUDGET, 2015). Despite the basic and infrastructure investment risks researches taken primarily by the public sector, the financial rewards of public risk-taking usually accumulates to the for-profit sector.

This risk-reward dynamic is dysfunctional and unsustainable, particularly when corporations avoid paying taxes that financially enables the State to take the long-term research risks that the for-profit sector cannot or will not take (Mazzucuto, 2014). A sustainable risk-reward dynamic would require, among other features, the for-profit sector to pay taxes (without loopholes or offshore tax havens) and market rate licenses for use of gover-

nment financed nanotechnology infrastructure, prototype production and regulatory science.

A further requirement to make the risk-reward dynamic sustainable for the public sector is that the commercialization of applied research, particularly derived from the State's basic research, be regulated. Such regulation would not only protect the State's investment in basic and applied research, but also the public whose taxes have financed most of that basic research. My thesis is that a state-owned and operated research entity, such as the Brazilian Agribusiness Research Corporation (EMBRAPA, 2014), cannot maintain society's support—no matter how often it claims that its “produtos y servicios [are] pela sociedade,”—so if Embrapa cannot demonstrate openly they have the data to show those products and services that do not harm workers, public health and the environment.

Although this presentation contains examples of applications of nanotechnologies and nanomaterials to agriculture and food (Berger, 2014), it is not a survey of agro-nanotechnology. A proper survey would take more time and space than what is afforded by a one hour lecture and these pages. However, the general logic for applying nanotechnology and nanomaterials to agriculture and food products is for what the United Nations of Food and Agriculture Organization (FAO) describes as “sustainable intensification” of agricultural production. The central focus of “sustainable intensification” is the even more efficient use of the natural resources for agriculture and food, measured by per hectare yield. (FOOD AND AGRICULTURE ORGANIZATION, 2009) In theory, such inputs as Nano-encapsulated pesticides and fertilizers would reduce the mass of inputs used, while increasing the bioavailability of toxins and nutrients respectively, contributing to higher yields. Additionally, there have been efforts to identify possible agro-nanotechnology applications that would be potentially “pro-poor.” (Gruere, Narod and Abbott, 2011).

The food and agro-nanotechnology examples sketched here are for illustrating some challenges of quantifying human, animal and environmental exposure to nanomaterials in such media as soil, water, and blood throughout the life cycle of a product. This life cycle includes the synthesis of ENMs (e.g. from gases to solids); their incorporation into products; the ENMs exposure of workers and the environment during production; and the final ENM environmental disposition, i.e., the “fate,” of that product and its components following the Nano-product’s useful life.

The scientific and budgetary difficulties of meeting these challenges may be the major reason why governments have not developed specific mandatory regulations to nanomaterials and nanotechnologies. ENMs have been detected and characterized in commercialized food and agricultural products without risking analysis and appropriated regulation to the specific properties of ENMs. (Peters et al, 2014). Therefore, there is an urgent need for Life Cycle Assessment (LCA) of ENMs and of the products in which ENMs are incorporated.

U.S. government oversight of nanotechnology through voluntary guidance to industry, rather than through mandatory rules

At a NNI co-sponsored workshop in July on research to quantify exposure to ENMs, Dr. Lloyd Whitman, of the U.S. Presidential Office of Science and Technology Policy, said the moment was ripe for “NNI 2.0,” i.e. a wave of commercialized nanotechnology enabled products (Suppan, 2015). However, NNI 2.0 required a “new EHS [Environmental Health and Safety] ecosystem” for which a faster through-put of robust exposure data would be required to enable regulatory scientists to assess risks, establish regulatory metrics, and expeditiously approve products for commerce (NATIONAL NANOTECHNOLOGY INITIATIVE, 2016, pp. 1-2).

To generate robust data with regulatory validity, several exposure scientists explained, they would need the cooperation of industry to do LCA of human, animal and environmental exposures to ENMs in commercialized products or products intended for commercialization. Performing LCA on laboratory created proxy Nano-products that would not suffice for regulatory purposes (NATIONAL NANOTECHNOLOGY INITIATIVE, 2016). Yet the U.S. government, and as far as I know, other governments, are not yet willing to require industry product and data submissions to regulatory scientists. Lacking robust, officially validated data to determine risks of products with ENMs that have entered into commerce, governments have sought to persuade nanotechnology product developers and nanomaterial manufacturers to submit voluntarily their own data.

For example, in three voluntary Guidance to Industry documents, the U.S. Food and Drug Administration (FDA), advises—but does not require— food, additive food and contact surface food manufacturers to be consulted with the agency before they commercialize products with ENMs (U.S. FOOD AND DRUG ADMINISTRATION, 2015). Mostly, importantly FDA advises food manufacturers that they should not assume food ingredients Generally Considered As Safe (GRAS) in their macro form will be considered GRAS in their Nano-scale form (U.S. FOOD AND DRUG ADMINISTRATION, 2015). Equally important is the FDA guidance concerning all products with ENMs under FDA's authority: the agency will not restrict its regulatory concern to ENMs in the 1-100 nanometer range. Preferably, the FDA will be interested in obtaining data and information from potential commercialization applicants for all material whose properties are attributable to their size up to 1000 nm (U.S. FOOD AND DRUG ADMINISTRATION, 2014b).

The FDA and other government regulators have good scientific cause to focus their regulatory concern on the ENM properties that are attributable to the size and configuration of the ENMs,

rather than limiting that concern to ENMs under 100 nanometers. For example, scientists have determined that polystyrene beads of up to 240 nanometers in diameter can pierce the human placental barrier, with possible harmful consequences for fetal development (WICK ET AL, 2014). Furthermore, one of the very few human volunteer studies about the effects of ingesting Nano-titanium dioxide has documented how those bio-accumulating ENMs pass from the human gut into the bloodstream (Pele et al, 2015). Nanoscale titanium dioxide has been detected in a wide range of foods commercialized in Australia, including candy (Reed et al, 2015).

Yet the paucity of studies about the effects of ingesting ENMs was reported by a government member of the Organization for Economic Cooperation and Development in a 2014 survey. Slightly more than 10 percent of the members reported that their scientists had studied gastro-intestinal exposure routes of ENMs (ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, 2015, Figure 3, p. 12). Nevertheless, the governments continue to allow the unregulated commercialization of food products with ENMs. For example, the U.S. NGO, the Center for Food Safety has published a searchable inventory of over 400 food and food contact surface products whose manufacturers claim to incorporate ENMs in their products (CENTER FOR FOOD SAFETY, 2015).

It was not clear to me in 2015 whether FDA's Guidance for Industry documents would succeed in securing the cooperation of nanotechnology product developers. The FDA had taken four years to draft the voluntary nanotechnology Guidance for Industry documents and two more to finalize them (Suppan, 2012). By contrast, U.S. regulation mandating industry action can take more than a decade to finalize and then the implementation of a rule can be frustrating into industry lawsuits against a rule and/or by a Congressional lobbying industry majority that refuses to fund the rules' implementation and enforcement.

(Postscript: NNI agency programs of voluntary guidance to industry continue to fail to secure industry cooperation. A recent case about this point is the discovery by Arizona State University's scientists that infant formula bought off the shelf contained ENMs, some of which are bio-accumulative in the infant body (Illuminato, 2016; Schoepf and Westerhoff, 2016). The formula manufacturers failed to heed the Food and Drug Administration's Guidance to Industry that product developers consult with the agency before marketing foods incorporating ENMs (U.S. FOOD AND DRUG ADMINISTRATION, 2014). The failure of FDA's program of voluntary consultation may result in health risks to the infants consuming the ENM fortified formula, to the caregivers inhaling the powdered formula while mixing it, and to the workers manufacturing it. (Illuminato, 2016).

Allowing the commercialization of food and agricultural products without regulation

Food and agricultural products incorporating ENMs have entered into commerce without regulation. Yet even governmental entities, such as the European Commission and the Dutch government, which have surveyed uses of ENMs in food and agricultural products (EUROPEAN FOOD SAFETY AUTHORITY, 2014), do not officially recognize this commercialization. There is no regulatory regime in place that would facilitate the commercialization of nanotechnology enabled food and agricultural products and require submission of data and information about such products for pre-market regulatory safety review and post-market monitoring. However, ten years ago, the governments began to study the use of ENMs in food products and the effects of those ENMs as they pass through the gastro-intestinal tract (DANISH MINISTRY OF THE ENVIRONMENT, 2013). ENMs may be added as ingredients to foods to achieve technical effects or they be taken up by food plants or animals from agricultural soil or water (NATIONAL NANOTECHNOLOGY INITIATIVE, 2016).

Nanoparticles can be taken up into plants and animals in a process called trophic transfer. Uptake of nanoparticles from soils into food crops is one potential exposure route for the general population, yet trophic transfer (from the food crop to the consumer) would also need to occur. Characteristics of the nanoparticle as it is accumulated and excreted are required to be better understood about the effect of factors such as particle size on the trophic transfer within a food web.

Non-governmental organization regulatory intervention and even litigation (CENTER FOR FOOD SAFETY, 2014) have failed to compel U.S. agencies to mandate the cooperation of nanotechnology product developers in submitting EMNs and products to pre-market regulatory review (SUPPAN, 2015b). Nor does it appear that the detection and quantification of ENMs in commercial food (e.g. Dekkers, 2010) will suffice to persuade governments to issue mandatory rules to regulate foods with ENMs.

What seems most likely to move governments to regulate nanomaterials and nanotechnologies is the prospect of watching their investment in the industry fail as private investors flee the technology (Kelleher, 2015). Governments can continue to let nanotechnology enable products and nanomaterials be commercialized with no LCA data to establish the metrics according to which the use of nanomaterials will not pose unacceptable risks to public, worker and environmental health. Or governments can pay for the science to develop such data and compel the cooperation of nanotech product developers to produce their own data from the normal use of the products they plan to commercialize. The Obama administration recently announced a new multi-million dollar public investment fund for the winners called *A Call for Nanotechnology Inspired Grand Challenges* (OFFICE OF SCIENCE AND TECHNOLOGY POLICY, 2015). Once again, the U.S. government has come to the rescue of the for-profit sector, as investors flee it.

However, generating robust LCA data for the main nanomaterials used in commerce on human, animal and natural environmental media of exposure requires basic scientific research, money for such research and the cooperation of product developers to generate its data with regulatory validity. Only governments can secure such resources and cooperation.

Challenges in the life cycle assessment of ENMs: detection and quantification of ENM exposures in food

It is not an easy task to detect, quantify and characterize ENMs in food and food-related products. The visualization and quantification measuring tools would be damaged if scientists attempted to directly measure ENMs in food, so a food paste simulacrum is, to oversimplify, put “under glass” (Singh et al, 2014). Likewise, with very few exceptions, studies of human ingestion of ENMs rely on *in vitro* methods, which, however ingenious, cannot capture the complexity of LCA *in vivo*.

Designing studies of ENMs in the gastro-intestinal tract has proven to be difficult, so the majority of studies undertaken have been *in vitro*. However, there is much more to be learned about the translocation and bioaccumulation of ENMs in the gastro-intestinal tract from the far more prevalent inhalation studies. As Robert Mercer’s research team has demonstrated, 12 days of laboratory rat exposure to multi-walled carbon nanotubes shows significant bioaccumulation after 336 days in both the liver and kidneys (Mercer et al, 2013). Scientists at the NNI/Consumer Safety Product Commission Quantifying Exposure to Engineered Nanomaterials from Manufactured Products (QEEN) workshop emphasized that they needed to be able to share unimpeded data by Confidential Business Information barriers, to avoid unnecessary experimental repetition beyond what was required for peer review (NATIONAL NANOTECHNOLOGY INITIATIVE, 2016). Money to develop data bases of LCA exposures

for the most widely used ENMS was a frequent request of the scientists.

However, equally important was the need to validate the analytic techniques and Nano-informatics models used to obtain the LCA results. Without such validation, the exposure scientists did not believe they could develop the data bases and metrics that regulators would need to ensure the pre-market safety of the major ENMs in their product matrices and human and environmental media. A fundamental impediment to develop the validated LCA exposure data required, a QEEN workshop panel concluded, was a basic lack of government knowledge about which ENMs were being used in which products and in how much quantities (NATIONAL NANOTECHNOLOGY INITIATIVE, 2016. p. 57).

A significant knowledge gap exists in knowing where and how large volumes of ENMs are actually processed and incorporated into products. Absent that knowledge, it is difficult to conduct valid, science-based estimates of risk to human or environmental health. The most constructive path to ensuring safe and sustainable innovation in nanotechnology development is one that is founded on substantive private-public collaboration, partnership, and knowledge sharing.

As Professor Paul Westerhoff, one of the most accomplished environmental engineers working on nanotechnology LCA, stated, after ten years of exposure studies of ENMs, exposure scientists still cannot tell workers whether a workplace exposure to ENMs is the cause of their illness. Nor can exposure scientists confidently provide expert witness for lawyers seeking to obtain redress for their clients who believe that ENM exposure has triggered their illness (Westerhoff, 2015).

The challenge of understanding the effects of ENMs on soil

LCA of ENMs in environmental media, particularly soil, is perhaps yet more difficult than LCA in human media because there is no law or protection policy to the components of soil health and fertility (TURBÉ ET AL, 2010. p. 11) as there is to human health and fertility. The lack of law to protect soil bio-diversity is difficult to understand, if only considering the trillions of dollars of annual economic value that result from soil biodiversity (Gnacadjia, 2010)

“Everything You Need to Know About Nano-pesticides,” an ironically titled article in *Modern Farmer*, a magazine oriented towards early technology adopters, broadly characterizes understanding about the economic and environmental risks that Nano-pesticides would pose to soil biodiversity: *It is not known whether the Nano-[pesticide] capsules would stick to the plants, clump on the soil surface or penetrate the ground and seep into streams and aquifers* (Gewin, 2015, Figure 1). A drawing that illustrates the article shows a method of pesticide application that is illegal in the United States, though still practiced in many countries, including the United States.

A European Food Safety Authority inventory of food and agricultural products with ENMs shows that authorities surveyed in EU member states and outside the EU reported 39 pesticide products commercialized with ENMs (Peters et al, 2014, Table 6). However, as far as we know, there is no hierarchy of industrial controls to protect pesticide manufacturer workers nor the farmworkers applying such pesticides.²

2 At the NNI workshop on quantifying ENM exposures, an administrator of the Occupational Health and Safety Administration told me that he was unaware of any U.S. government research to develop protective equipment. Clothing and procedures for applying pesticides with ENMs.

Readers of the *Modern Farmer* article are lead to believe that *Manufacturers of Nano-capsules for pesticides already approved for use will not be required to prove determine the fate of the Nano-formulations in the environment* (Gewin, 2015, Figure 1). It is far from certain whether the Environmental Protection Agency (EPA), which approves pesticides for commercial use, will agree with this point of view. The International Center for Technology Assessment and the Center for Food Safety, U.S. NGOs, are suing the EPA for having approved a Nano-anti-microbial, advertised as a pesticide, without a public hearing as required by law (INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, 2015).

If the EPA does come to agree that Nano-pesticides can be commercialized without a Nano-specific risk assessment, the environmental and public health impacts elsewhere implied in the ingeniously simplified *Modern Farmer* illustration could cause great harm to agricultural soil, water, workers, families and communities. Furthermore an EPA strategy to deregulate Nano-encapsulated pesticides under current pesticides regulations that could damage the public reputation of nanotechnology in general and hence to the government's \$22 billion plus (as of 2015) NNI investment.

Even if nanotechnology LCA develops enough data to provide the scientific basis for legal redress, who will defend and seek redress for the micro-arthropods and the other engineers of soil health whose exposure to ENMs has been shown to reduce soil-biomass and the ability of earthworms to carry out their soil-building functions? (Colman, 2013) The Center for the Environmental Implications of Nanotechnology (CEINT), a multi-university consortium funded by NNI, has conducted mesocosm simulations of agricultural field exposure to ENMs for up to a year.

The most likely present source of agricultural soil exposure to ENMs is the treated sewage that EPA calls "bio solids." (ENVI-

ENVIRONMENTAL PROTECTION AGENCY, 2016) For the farmer who applies the bio solids to the soil, often when they are dry, the possibility of inhaling ENMs in the airborne bio solids would be a recurrent, if infrequent possibility. A photo in my October 20, 2015 Power Point presentation of a typical dispersion of a dry bio solid should establish this possibility. The NNI 2014 Strategic Plan did not recognize bio solid application as an LCA source, though it identifies landfills with Nano-coated industrial components as an LCA source (NATIONAL NANOTECHNOLOGY INITIATIVE, 2014). IATP's comment on the draft Strategic Plan argued unsuccessfully that bio solids should be identified by NNI agencies as a LCA source (Institute for Agriculture and Trade Policy, 2013).

As I wrote in a 2013 essay, there is no law in the world that protects soil health, perhaps because of the scientific complexity of doing so. Yet the economic costs of abusing soil through erosion, and contamination have been estimated globally at \$13 trillion per year. Farmers test the soil for its most commercially important nutrients, but the microbial health of soil and particularly of soil engineers is advanced by good agricultural practices. These practices include planting cover crops that are supportive to both of cash crops, and pasture grazed livestock (Suppan, 2013).

The U.S. National Institute for Food and Agriculture (NIFA) has funded research in the effects on agricultural plants in hydropo-
nic or sterilized laboratory soil, to better control the results of the experiments (E.g., Dimkpa et al, 2012). When NIFA funded research has attempted to measure the impact of ENMs on the soil's capacity to maintain or increase its fertility, they often test the capacity of earthworms, the charismatic animal of soil science, to perform their soil building functions while living in soil dosed with ENMS, e.g. carbon nanotubes.

The pioneering work of CEINT has been to perform long term experiments in real soil in mesocosms (essentially, large tubs) within a controlled greenhouse environment, which enables con-

trols to better measure the complexity of dosing the soil with doses of ENMs most frequently found in bio solids. Without going into great detail about these experiments, it is fair to they follow the maxim of one of the CEINT deputy directors, Professor Greg Lowry of Carnegie Mellon University. During one of his presentations at the QEEN workshop, he said that a lesson learned at CEINT is that understanding the complexity of the system, in this case soil, in which the ENMs are introduced, is at least as important as ensuring that the bio solid ENMs that are introduced into the soil are in uniformly applied doses (Lowry, 2015, Slide 7).

One of the more remarkable findings of Professor Benjamin Cole's research group at Duke University, a CEINT member, is not that the dosing of soil with Nano-silver reduced soil biomass (a soil health proxy indicator), which was expected. Entirely unexpected was that a Nano-silver slurry applied to soil released nitrous oxide, a greenhouse gas about 225 times as potent as carbon dioxide. The release was of relatively short duration, beginning at about day 8 of the experiment and ending at day 50 as the nitrous oxide flux converged with that of bio solid slurry without silver nanoparticles (Colman et al, 2013, p. 5).

The climate change consequences of the inadvertent application of Nano-silver in bio solids to agricultural land are not small. Repeat applications of bio solids are not infrequent, because it is a cheap form of fertilizers at a time when to U.S. farmer cost of production is considerably higher—e.g. about 30 percent higher—than 2015 prices received for those crops on a bushel unit basis. (Schafer, 2015) U.S. farmers spent about \$28.5 billion on fertilizers in 2012, a 56.7% increase over 2007. (U.S. DEPARTMENT OF AGRICULTURE, 2014, Table 4) It will be difficult for many U.S. farmers to give up such an apparently cheap form of fertilizer as bio solids. The current unsustainable economic situation of industrial crop production will continue to be made possible by U.S. government investment in the form of subsidies to compensate for agri-business market failure.

Conclusion: Towards a Life Cycle Assessment of ENMs in Humans, Animals and the Natural Environment: A Prerequisite for the Regulation of Nanotechnologies and Nanomaterials

I summarize the current state of play in the U.S. pre-regulation of ENMs and nanotechnologies in terms of the dynamics at work in the aforementioned NNI workshop on quantifying LCA exposure to ENMs in products.³ This summary likely oversimplifies the U.S. for-profit and public sector situation, but this summary state of play conclusion is not grossly inaccurate.

- The White House Office of Science and Technology Policy wants “NNI 2.0,” a large increase in nanotechnology product commercialization, for which it requires a “EHS [Environment, Health and Safety data] ecosystem” to provide the exposure data necessary to realize “NNI 2.0”(Suppan, 2015)⁴.
- The for-profit nanotechnology sector wants to continue to benefit from the government’s basic research, testing services and prototype manufacturing, particularly in the National Institute for Standards and Testing. But it does not want any mandatory rules for pre-market safety reviews and post-marketing monitoring.
- Exposure scientists wants more funds for both individual exposure studies and for the building of LCA exposure databases, so the scientists can be more promptly benefited from each other’s work. They need to be able to share data and experimental design to validate experimental methods and models,

³ This lecture was given on 20.8.15 and reflects my experience of the NNI QEEN workshop before the workshop report was published in 2016. I have tried to reconcile my experience of the workshop with the official report about it.

⁴ Dr. Whitman’s comments do not form part of the NNI report on the QEEN workshop but are recalled in my near contemporaneous blog <http://www.iatp.org/blog/201507/no-small-task-generating-robust-nano-data>

a first necessary step towards building that data base. They need the cooperation of nanotechnology product developers to do LCA of their products, in order that their data base has regulatory validity. Current Confidential Business Information barriers must be greatly reduced to use robust exposure data to build a robust regulatory system (Nielsen, 2013 p. 1).

- Trade union workers, farmers and consumer organizations have inadequate information and lack a hierarchy of controls to protect human, animal and environmental health and safety. Development of such information and controls in a program of public engagement is an urgent public policy needed for nanotechnology.

Acknowledgements

This article summarizes much of my October 20, 2015 presentation to the XII Seminanosoma at the Universidade Federal de Sergipe. However, that presentation depended to no small extent on charts and photos, all of which are not reproduced in this summary. Some of these photos and charts are referenced in the cited documents. As a result, some topics of the presentation are less present in this summary. I am very grateful to the Universidade Federal de Sergipe, to Professor Tania Magno and to the Brazilian Research Network on Nanotechnology, Society and Environment (Renanosoma) for the opportunity to present the following research.

Bibliography

CENTER FOR FOOD SAFETY et al. v. **Environmental Protection Agency**. Filed in U.S. District Court or the District of Columbia. 16.12.2014. Available at http://www.centerforfoodsafety.org/files/2014-12-16-dkt-1--pls--complaint_78869.pdf Accessed 27.9.2016.

CENTER FOR FOOD SAFETY. **Nanotechnology in Our Food**. 2015. http://salsa3.salsalabs.com/o/1881/p/salsa/web/common/public/content?content_item_KEY=14112 Accessed 27.9.16.

COLMAN, Benjamin et al, "Low Concentrations of Silver Nanoparticles Produce Adverse Ecosystem Responses under Realistic Field Scenario," **Plos One**, 27.2.2013. Available at <http://journals.plos.org/plosone/article/asset?id=10.1371/journal.pone.0057189>.PDF Accessed 28.9.2016.

DANISH MINISTRY OF THE ENVIRONMENT. **Systemic Absorption of Nanomaterials by Oral Exposure**. 2013. Available at https://www.researchgate.net/publication/303444435_Systemic_Absorption_of_Nanomaterials_by_Oral_Exposure Accessed on 27.9.2016.

DEKKERS, Susan et al, "Presence and risks of nano-silica in food products," **Nanotoxicology**, 2010. Available at <http://www.pubpdf.com/pub/20868236/Presence-and-risks-of-nanosilica-in-food-products> Accessed 27.9.16.

DIMKPA, Christian O. Joan E. McLean, David W. Britt, and Anne J. Anderson. Biomodification and Bioremediation of Ag, ZnO and CuO Nanoparticles with Relevance to Plant Performance in Agriculture. **Industrial Biotechnology** *Industrial Biotechnology*. December 2012. Available at http://www.academia.edu/25515029/Bioactivity_and_Biomodification_of_Ag_ZnO_and_CuO_Nanoparticles_with_Relevance_to_Plant_Performance_in_Agriculture Accessed 28.9.16.

ENVIRONMENTAL PROTECTION AGENCY. **Agriculture: Nutrients and Fertilizers**. 3.8.2016. Available at <https://www.epa.gov/agriculture/agriculture-nutrient-management-and-fertilizer> <http://www.epa.gov/agriculture/tfer.html> Accessed 28.9.2016.

EMBRAPA (Brazilian Agribusiness Research Corporation), (2014) Annais do VIII Workshop do Nanotecnologia Aplicada a Agronegócio.

GEWIN, Virginia. Everything You Need to Know About Nano-pesticides. **Modern Farmer**, 21.1.2015, Figure 1, "Nanopesticides: Tiny particles, big questions." Available at <http://modernfarmer.com/2015/01/everything-need-know-nanopesticides/> Accessed 28.9.16.

GNACADJA, Luc. The Trillions Worth of Soil Biodiversity, **In Depth News Viewpoint**, 18.6. 2010. Available at <http://www.other-news.info/2010/06/the-trillions-worth-soil-biodiversity/> Accessed 28.9.2016.

GRUÈRE, Guillame, Claire Narrod and Linda Abbott, **Agriculture, Food and Water Nanotechnologies for the Poor: Opportunities and Constraints**. International Food Policy Research Institute, Policy Brief 19, June 2011. Available at <https://www.ifpri.org/publication/agriculture-food-and-water-nanotechnologies-poor> Accessed 26.9.2016.

ILLUMINATO, Ian, **Nanoparticles in baby formula: Tiny new ingredients are a big concern**, Friends of the Earth, May 2016. Available at http://webiva-downton.s3.amazonaws.com/877/eb/2/8482/FOE_NanoBabyFormulaReport_13.pdf Accessed 27.9.2016.

INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT AND CENTER FOR FOOD SAFETY V. Environmental Protection Agency. Petition for Review. Filed in the U.S. **Court of Appeals for the Ninth Circuit**. 27.7.2016. Available at http://www.centerforfoodsafety.org/files/2015-7-27-nanosilva-9th-cir-petition-for-review_18270.pdf Accessed 28.9.2016.

INSTITUTE FOR AGRICULTURE AND TRADE POLICY. Comment on the draft National Nanotechnology Initiative Strategic Plan. 16.12.2013. Available at http://www.iatp.org/files/Comment_on_the_National_Nanotechnology_Initiative_NNI_draft_Strategic_Plan%20.pdf

KELLEHER, Kevin. **Here's Why Nobody's Talking About Nanotech Anymore**. *Time*, October 9, 2015. Available at <http://time.com/4068125/nanotech-sector/> Accessed on 27.9.2016.

LOWRY, Greg. **Measuring and Modeling Exposure to Nanomaterials in Complex Systems**. June 2015. Available at http://www.nano.gov/sites/default/files/pub_resource/201_lowry_measuring_modeling_exp_to_nps_in_complex_systems.pdf Accessed 28.9.2016.

MAZZUCATO, Mariana. **The Entrepreneurial State: Debunking Public vs. Private Sector Myths**, London, Anthem Press, 2014.

MERCER, Robert et al, **Determination of the Fate of Inhaled Nanoparticles**. *Particle Fiber Toxicology*, 2013. Available at http://www.nano.gov/sites/default/files/pub_resource/205c.4_mercer_fate_of_inhaled_nanoparticles.pdf Accessed 9.28.2016

NATIONAL NANOTECHNOLOGY INITIATIVE, **Quantifying Exposure to Engineered Nanomaterials [QEEN]**: Addressing Environmental, Health, and Safety Implications, 2016. Available at http://www.nano.gov/sites/default/files/pub_resource/queen_workshop_report_2016.pdf Accessed 26.9.2016.

NATIONAL NANOTECHNOLOGY INITIATIVE. **Supplement to the President's 2016 Budget**. 11.3.2015. Available at <http://www.nano.gov/node/1326> Accessed 28.9.2016.

NATIONAL NANOTECHNOLOGY INITIATIVE. **Strategic Plan**, 2014, at 34. http://www.nano.gov/sites/default/files/pub_resource/2014_nni_strategic_plan.pdf

NIELSEN, Kaare M. **Biosafety Data as Confidential Business Information.** *PLoS Biology* 11(3) 5.3.2013. <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1001499> Accessed 28.9.2016.

OFFICE OF SCIENCE AND TECHNOLOGY POLICY. **A Call for Nanotechnology Inspired Grand Challenges of the Next Decade.** June 17, 2015. <https://www.federalregister.gov/articles/2015/06/17/2015-14914/nanotechnology-inspired-grand-challenges-for-the-next-decade> Accessed 27.9.2016.

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT. **Analysis of the Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials.** July 2015. Available at [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2015\)20&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2015)20&doclanguage=en) Accessed 27.9.2016.

PELE, Laetitia et al. Pharmaceutical/food grade titanium dioxide particles are absorbed into the bloodstream of human volunteers. **Particle Fibre Toxicology.** 2015; 12: 26. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4557898/> Accessed 27.10.2016.

PETERS, Ruud et al. **European Food Safety Authority.** Inventory of Nanotechnology applications in the agricultural, feed and food sector. 2014. Available at <http://online-library.wiley.com/doi/10.2903/sp.efsa.2014.EN-621/abstract> Accessed 26.9.2016.

REED, Robert et al. **Detecting Engineered Nanomaterials in Processed Foods in Australia.** Arizona State University, prepared for Friends of the Earth Australia, 18.8.2015. <http://emergingtech.foe.org.au/wp-content/uploads/2015/09/FoE-Aus-Report-Final-web.pdf> Accessed 27.9.2016

SCHAFER, Lee. Farmers are planning for the second bad year in a row. **Minneapolis Star Tribune,** 1.8.2015. Available at <http://www.startribune.com/farmers-are-planning-for-the-second-bad-year-in-a-row/320331541/>

SCHOEPEF, Jared and Paul Westerhoff. **Detecting Engineered Nanoparticles in Baby Formula,** Arizona State University, 4.5.2016. Available at http://webiva-downton.s3.amazonaws.com/877/90/d/8141/ASU_FOE_Baby_Formula_Report_May_4_2016_FINAL.pdf Accessed 28.9.2016.

SINGH, Gurmit et al, **Measurement Methods to Detect, Quantify and Characterize Engineered Nanomaterials in Foods.** Comprehensive Reviews in Food Science and Food Safety, 2014. http://www.nanotechia.org/sites/default/files/files/Singh_2014_Methods_detect_crf312078.pdf Accessed 27.9.2016.

SUPPAN, Steve. **No Small Task: Generating Robust Nano-Data.** 16.7.2015. Available at <http://www.iatp.org/blog/201507/no-small-task-generating-robust-nano-data> Accessed 28.9.2016.

SUPPAN, Steve. **Suing EPA for failure to regulate nano-pesticides**, 2.4.2015b. Available at <http://www.iatp.org/blog/201504/suing-epa-for-failure-to-regulate-nano-pesticides-0> Accessed 28.9.2016

_____. **FDA to industry: please call us if you put nanomaterials in food**. 20.8.2014. Available at <http://www.iatp.org/blog/201408/fda-to-industry-please-call-us-if-you-put-nanomaterials-in-food> Accessed 26.9.2016.

_____. **Nanomaterials in Soil: Our Future Food Chain?**. Institute for Agriculture and Trade Policy, March 2013. Available at http://www.iatp.org/files/2013_04_23_Nanotech_SS.pdf Accessed 28.9.2016.

_____. **At least four years in the making: Draft FDA guidelines on nanotechnology in food and cosmetics**. 2.5.2012. Available at <http://www.iatp.org/blog/201205/at-least-four-years-in-the-making-draft-fda-guidelines-on-nanotechnology-in-food-and-cos> Accessed 27.9.2016.

TURBÉ, Anne et al. European Commission Directorate General Environment, **Soil biodiversity: functions, threats and tools for policy makers**. February 2010. Available at http://ec.europa.eu/environment/archives/soil/pdf/biodiversity_report.pdf Accessed 28.9.2016.

U.S. DEPARTMENT OF AGRICULTURE. **Census of Agriculture: 2012 Census Highlights**. May 2014. Available at https://www.agcensus.usda.gov/Publications/2012/Online_Resources/Highlights/Farm_Economics/ Accessed 28.9.2016.

U.S. FOOD AND DRUG ADMINISTRATION, **Guidance for Industry: Assessing the Effect of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Surfaces, Including Food Ingredients that Are Color Additives**. June 2014. Available at <http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300927.pdf> Accessed 27.9.2016.

_____. **Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology**. June 2014 b. Available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM401695.pdf> Accessed 27.10.2016.

_____. **Nanotechnology**. 5.8.2015. Available at <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm> Accessed 26.9.2016.

WESTERHOFF, Paul. **The Application of exposure science to the life cycle**. July 2015, Slide 2. Available at https://www.nano.gov/sites/default/files/pub_resource/102_westerhoff_introduction_lca_and_exposure_science.pdf Accessed 28.9.2016.

WICK, Peter et al. Barrier Capacity of Human Placenta for Nano-sized Materials. **Environmental Health Perspectives**, March, 2010. Table 6. Available at <http://www.ncbi.nlm.nih.gov/pubmed/20064770> Accessed 26.9.2016.

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