Nanomaterials and Risk: Appropriate Use of the Technical Data

Prepared by
Vicki L. Colvin, Ph.D., Center for Biological and Environmental Nanotechnology, Rice University

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The safety of sunscreens used by millions of consumers has been the subject of great debate in 2006. Sunscreens represent a multi-million dollar market, and their consistent use is thought to reduce substantially the incidence of skin cancer, a disease with more than 1 million new cases diagnosed annually in the US alone. Titanium dioxide has been used as a sun-blocking pigment in sunscreens for decades; in the mid-1990s advances in nanotechnology permitted the size of the pigments to be reduced to below 100 nm. Similar advances were also applied to a different material, zinc oxide, and today it is estimated that 30% of the sunscreens sold commercially contain these inorganic nanoparticles. By shrinking the size of sunscreen pigments, manufacturers generate products that can be applied very smoothly and appear clear to the eye. The issue addressed in two recent technical reports, and in this month's FDA public commentary, is whether shrinking the size of the pigments leads to any new toxicological properties.

A non-governmental organization, Friends of the Earth, released a report in May of 2006 characterizing the level of regulation of components of these sunscreens as *"… one of the most dramatic failures since asbestos …"* This September, the Cosmetic, Toiletry and Fragrance Association (CTFA), a trade association funded by industry, released a statement claiming *"The general scientific consensus is that there is no risk to human health"* from these materials. The statements from both organizations demonstrate selective use of the scientific literature and set the stage for an ineffective and polarized public dialog on nanotechnology's risks and benefits.

The Friends of the Earth report presents a reasonably complete accounting of the recent technical literature, but the technical review does not connect well to the ultimate recommendations. At several points in the technical report, the authors acknowledge seemingly conflicting technical data in the literature on nanomaterials and health effects, yet these nuances are not apparent in the report's summary. For example, the report admits that insufficient information about *"...particle translocation across skin..."* means *"...the jury is still out...."* Yet, the report concludes regulatory negligence and calls for *"a moratorium on the commercialization of nanoproducts until the necessary safety research has been conducted."* [1] The Friends of the Earth analysis also generalizes from the specific cases of particular nanostructures found in one formulation to the behavior of all nanoproducts. Thus, the report cites groups of papers on one nanomaterial type (e.g. carbon sixty) and then later in the report refers to those results as the basis for taking action on all nanoparticle types. This tendency to overgeneralize is particularly

apparent in the report summary, and in the more extensive policy recommendations laid out in the CTA legal petition to the FDA on behalf of FOE and a coalition of other advocacy groups.[2]

The CTFA press release and associated report shared with the FOE report a similar level of technical depth but draws very different conclusions. As in the Friends of the Earth report, there are disconnects between CTFA's short public statements and the longer technical report. For example, the press release holds that the *"…overwhelming weight of the scientific evidence states that these substances (nanotitania) are safe and non-toxic…"*[3] yet the full report from the same organization cites several publications that demonstrate oxidative damage in biological systems from nanoscale titania. [4] In contrast to the Friends of the Earth report the CTFA report does capture the diversity of nanoparticle composition and the related diversity in biological response. In their analysis, however, these data are used to justify a different overgeneralization, namely, *"…the size of these nanoparticles does not make them inherently different in terms of toxicity..."*. [3] The toxicity of nanoparticles will likely be caused by several physio-chemical properties, but this fact does not preclude size as being an important factor in defining biological properties for some systems.

Interestingly both reports were in good agreement that the technical literature on many important points is equivocal. This is perhaps why the detailed reports are not substantially different and cover much of the same literature. What is striking, however, is how each organization reacted differently to the current studies. To the CTFA the uncertainty was an argument <u>not to regulate</u> based on any particular parameter because generalizations about properties may be unreliable. Friends of the Earth, on the other hand, saw equivocation in the technical data as a sign that <u>regulation must proceed quickly</u> because there is technical data suggesting hazard for some sets of nanomaterials. Thus, the disparity between these two viewpoints is really not grounded in the technical literature.

Recommendations

- We urge all stakeholders to permit the debate about nanotechnology's risks and benefits to occur at the highest possible technical level.

- All technical information used to form the basis for the first policy decisions in this area should be publicly available. The benefits of an open review of information at such a critical time in nanotechnology's development outweigh any possible loss to business due to confidentiality. We urge companies to not only make available toxicology and testing data, ideally through peer-reviewed channels, but also to provide data to support the efficacy of nanopigments compared to comparable organic materials.

- Non-governmental organizations should continue to monitor the technical literature and highlight areas where more focused research is needed. Databases

such as the one offered by ICON on EHS publications should help, and in time will contain more integrative information to help educate interested parties.

Whether the benefits of using sunscreens containing nanoparticle pigments outweigh their risks is a question not yet resolved in the peer-reviewed literature. We hope that while the science remains uncertain, governmental organizations like the FDA will base their policy decisions on a balanced analysis of the peer-reviewed and publicly available scientific literature. General principles of risk management, which rely on good monitoring programs and investments in research, are well-suited to these necessarily uncertain technical times.

This statement has not been approved as an official document of the International Council on Nanotechnology by its editorial board and should be considered the personal opinion of the author.

Resources

[1] Friends of the Earth Report. Nanomaterials, sunscreens and cosmetics: Small Ingredients, Big Risks. http://www.foe.org/camps/comm/nanotech/nanocosmetics.pdf.

[2] CTA Legal Petition on FDA's Failure to Regulate Health Threats from Nanomaterials http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf

[3] CTFA Press Release. Cosmetic Industry Files FDA Comments on Use of Nanoparticles in Personal Care Products http://www.ctfa.org/Template.cfm?Section=CTFA_News&template=/ContentManagement/ContentDisplay.cfm&ContentID=4111

[4] Comments by the CTFA to FDA on Nanotechnology http://www.ctfa.org/Content/ContentGroups/News/Latest_Statements/CTFANanotechnologyCommentstoFDA.pdf