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Executive Summary

Legal Petition on FDA's Failure to Regulate Health Threats from Nanomaterials

On May 16, 2006, the International Center for Technology Assessment (CTA) and a coalition of consumer, health, and environmental groups filed a formal legal petition with the Food and Drug Administration (FDA), calling on the agency to address the human health and environmental risks of untested and unlabeled nanomaterials in consumer products. The petition is the first U.S. legal action filed on the potential human health and environmental risks of nanotechnology.

Nanotechnology and Nano-products have arrived

Nanotechnology and consumer products containing engineered nanoparticles have arrived and represent the crest of a wave of nanomaterial products spanning many technologies. Hundreds of consumer products composed of engineered nanoparticles, including many nano-cosmetics and nano-sunscreens, are widely available. But "nano" does not simply mean tiny or smaller; it means fundamentally different. Engineered nanoparticles have fundamentally different properties from their bulk material counterparts—properties that also create unique human health and environmental risks—which necessitate new health and safety testing paradigms.

FDA's erroneous and ill-advised regulatory stance

FDA has regulatory authority over many nanomaterial products, including nano-sunscreens and nano-cosmetics. Yet the agency has taken no steps to formally recognize the inherent differences of nanomaterials and address their associated new risks to human health and the environment. The agency's current stance is that its bulk material testing methodologies and existing regulatory framework are adequate, and in some cases, including with nano-sunscreens, the agency has assumed the safety of nanomaterial products based on the previous assessment of bulk scale counterparts. This stance flies in the face of the universal scientific assessment of engineered nanoparticles, which is that the adverse effects of nanoparticles cannot be reliably predicted or derived from the known toxicity of the bulk material.

The Petition

The petition has two distinct halves, one dealing with nano-product regulation generally and one focusing specifically on nano-sunscreen regulation. Section one documents the existing body of scientific evidence studying nanomaterial risks stemming from their unpredictable toxicity and seemingly unlimited mobility. It requests FDA issue a formal opinion on engineered nanoparticles in light of this evidence, amend its regulations to include nanotechnology definitions necessary for proper regulation, and enact comprehensive nano-product regulations, including nanomaterial-

specific toxicity testing and mandatory nano-product labeling. In addition, section one request that any current or future FDA programs for nano-products include the consideration of human health and environmental impacts in accordance with the National Environmental Policy Act (NEPA), including that FDA conduct a Programmatic Environmental Impact Statement.

The petition's second half focuses on engineered nanoparticles of titanium dioxide and zinc oxide used in nano-sunscreens. Sunscreens are classified by FDA as human drugs, unlike many other personal care products, and are consequently subject to more rigorous FDA regulation. Any new drug manufacturer must submit a new drug application with evidence supporting the drug's safety and efficacy. The commercial appeal of nano-sunscreens is that they are transparent or "cosmetically clear" because of the nanoparticles' fundamentally different properties. The engineered nanoparticles are also patented for their profitable novelty. Yet in the agency's first and only word on sunscreens, a 1999 regulation, FDA considered engineered nanoparticle ingredients in these sunscreens a mere reduction in size and not a new drug ingredient, permitting sunscreen manufacturers to sell nano-sunscreens based on the safety assessment of bulk material sunscreens.

The petition asks FDA to reconsider its 1999 equivalency stance on nano-sunscreens, again pointing out that it is contrary to the universal scientific opinion regarding the fundamental differences and unique dangers of engineered nanoparticles. For example, the zinc oxide and titanium dioxide nanoparticles used in nano-sunscreens raise red flags for scientists, since these particles could be inhaled and/or are capable of penetrating the skin and circulating throughout the body. Studies have shown them to be photoactive in some cases, producing free radicals and causing DNA damage to human skin cells when exposed to UV light. The petition calls for regulations classifying nano-sunscreens as new drug products which require premarket review of health and safety evidence. Because nano-sunscreens are currently sold without such testing or review by FDA, the petition requests FDA declare those products an imminent hazard to public health and order manufacturers cease production until FDA nanotechnology regulations are developed and implemented.

The petitioners

The legal petition was filed in conjunction with a report on the dangers of nano-sunscreens and nano-cosmetics by Friends of the Earth (FOE). The petitioner organizations are CTA, FOE, Greenpeace International, The Action Group on Erosion, Technology, and Concentration (ETC Group), Clean Production Action, The Center for Environmental Health (CEH), Our Bodies Ourselves, and The Silicon Valley Toxics Coalition (SVTC).

Read the full petition [here](#)