

22 November 2006

Jim Jones, Director Office of Pesticide Programs U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

### Re: Registration of Nanosilver as a Pesticide under FIFRA

Dear Mr. Jones:

The Natural Resources Defense Council (NRDC) commends the EPA Office of Pesticide Programs' recent decision to regulate the use of nanosilver as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") as reported in the Daily Environment Report on November 21.<sup>i</sup> This action is an important step in the right direction; however, there are currently more than 40 consumer products in the marketplace that contain nanosilver, some of which either expressly make pesticidal claims or imply pesticidal effectiveness and none of which are currently registered with EPA. EPA is obligated to examine these products and require registration for any product that uses nanosilver as a biocide. Furthermore, we are confident that once EPA has specifically examined nanosilver pursuant to the appropriate FIFRA risk assessment provisions, EPA will recognize the significant harm that this substance inflicts on the environment (particularly on aquatic organisms) and will be compelled either to prohibit or significantly restrict its use.

With the expanding commercial penetration of nanotechnologies into various industries, the world has seen an explosion in the use of nanoparticles in common consumer products. One manifestation of this phenomenon is the extensive use of nanosilver as an antimicrobial pesticide with the potential for widespread population exposure and run-off into waterways. In the U.S., among other examples, Samsung and The Sharper Image are marketing various products that use nanosilver as an antimicrobial agent. In particular, Samsung has developed a washing machine that uses SilverCare<sup>TM</sup> Technology to clean clothes and kill biological organisms by releasing nanosilver ions into the washwater, and The Sharper Image has developed socks, slippers, and food containers impregnated with

nanosilver. In addition to these examples, however, there are numerous other consumer products that contain nanosilver and that also pose serious risks to the environment.

In connection with its reported decision to regulate the use of nanosilver in washing machines, presumably EPA has recognized that nanosilver is a pesticide under the applicable provisions of FIFRA. Consequently, as discussed below, EPA is obligated to examine and require the registration of any product that uses nanosilver for its biocidal qualities.

### Nanosilver is a pesticide that must be regulated under 7 U.S.C. §136a

FIFRA requires that pesticides and pesticide products be registered before they can be legally sold in the United States. 7 U.S.C. §136a. To comply with FIFRA, a pesticide must be evaluated through an extensive process to assess any potential risks it may pose to human health or the environment. If EPA makes a finding that a pesticide will cause unreasonable adverse effects on the environment, EPA must deny its registration. 7 U.S.C. §136a(c)(5)(C).

A pesticide is, among others, "any substance... intended for... destroying...any pest," and "fungus, bacterium, virus, or other microorganisms" are considered pests. 40 C.F.R. 152.3. Additionally, a pesticide product is "a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold." 40 C.F.R. § 152.3. While generally deodorizers, bleaches and cleaners are not pesticides subject to FIFRA regulation, a "pesticidal claim" on the label or in connection with the sale or distribution of the product will trigger the registration requirement for pesticides. 40 C.F.R. §152.10(a).

The following discussion of two products that use nanosilver as a pesticide provides a compelling illustration of why immediate EPA action is both legally required and essential to address more broadly the use of this potentially harmful substance in consumer products.

### The Sharper Image's FresherLonger™ Miracle Food Storage Containers

The Sharper Image has been marketing nanosilver-treated slippers, socks, and food containers. Recently, the company removed public statements of pesticidal claims without removing nanosilver from the products; this action denies the public's right to know the active ingredient of these products. This is a direct violation of FIFRA, which requires that pesticides must be registered to be sold in the United States. 7 U.S.C. §136a(a).

The Sharper Image currently claims on its website that its "exclusive FresherLonger<sup>™</sup> Miracle Food Storage Containers are made of specially treated air- and odorimpermeable polypropylene and they feature a patent-pending, airtight silicone-gasket locking system that helps to retard spoilage" but, no longer makes specific references to either nanosilver or to biocide activity.<sup>ii</sup> However, by searching archived webpages, an April 2006 version of the same advertisement includes the following additional description:

FresherLonger containers are infused with silver nanoparticles because silver (yes, the metal found in silverware) is safe and naturally anti-germ, anti-mold and anti-fungus. In tests comparing FresherLonger to conventional containers, the 24-hour growth of bacteria inside FresherLonger containers was reduced by over 98 percent because of the silver nanoparticles!<sup>iii</sup>

Moreover, the archived Sharper Image website makes the following specific pesticidal claim:

FresherLonger<sup>™</sup> Miracle Food Storage Containers Are Naturally Anti-Germ, Anti-Mold & Anti-Fungus...Silver in microscopic particle form is a safe, medically proven antibacterial agent. That is why silver nanoparticles are infused into the polypropylene containers of the FresherLonger system. Compared to your regular food storage containers, tests showed the 24-hour growth of bacteria inside FresherLonger containers — with antibacterial silver nanoparticles — was reduced by over 98 percent.<sup>iv</sup>

The archived website even includes a specific description of the nanosilver ingredient:

Created by advanced nanotechnology ("nano" indicating one billionth), these silver nanoparticles average only about 25nm (nanometers) in diameter — 25 billionths of a meter; one 200 thousandth of a human hair. Their natural color gives FresherLonger Miracle Food Storage containers their distinctive golden hue.<sup>v</sup>

EPA regulations impose certain labeling requirements for pesticide products. A statement identifying the name and percentage by weight of all active ingredients and all inert ingredients must be placed on any pesticide product. 40 C.F.R. §156.10(g)(1). Removal of pesticidal claims from its products does not shield the products from FIFRA regulation. Pesticidal claims will bring deodorizers and cleaning agents, which are normally not classified as pesticides, within the purview of FIFRA regulation. However, these Sharper Image products go beyond deodorizing and cleaning, and they fall clearly within the definition of a pesticide. The claims of the "Anti-Germ, Anti-Mold & Anti-Fungus" qualities of the FresherLonger™ containers underscore the nanosilver's ability to "destroy" "any fungus [or] bacterium." Accordingly, failure to identify nano-scale pesticide ingredients should not be an excuse to circumvent the FIFRA registration requirements.

# The Samsung washing machine with SilverCare<sup>™</sup> Technology is a pesticide product under 40 CFR §152.3

Samsung has produced a line of washing machines incorporating its SilverCare<sup>™</sup> Technology, which releases nanosilver ions into the water during the laundering process. The manufacturer touts the SilverCare<sup>™</sup> Technology's "superb microbe killing capabilities…" in its marketing campaign.<sup>vi</sup>

As noted in the report of EPA's decision to regulate nanosilver, the Agency's earlier determination that the Samsung washing machine with SilverCare<sup>TM</sup> Technology is a "device" and not subject to the same rigorous evaluations as pesticides was inappropriate.<sup>vii</sup>

Under FIFRA, a device is "any instrument or contrivance...which is intended for trapping, destroying, repelling, or mitigating any pest...; but not including equipment used for the application of pesticides when sold separately there from." 7 U.S.C. §136(h). Furthermore, the regulations note that pesticide product "includes any physical apparatus used to deliver or apply the pesticide if used to deliver or apply the pesticide if used to deliver or apply the pesticide if distributed or sold with the pesticide." 40 C.F.R. §152.3.

Without doubt, nanosilver is a pesticide active ingredient. The Samsung washing machine with SilverCare<sup>TM</sup> Technology works by releasing "100 quadrillion silver ions" into the water during the wash and rinse cycles to kill microbes on the clothes. <sup>viii</sup> As such, the Samsung washing machine is an apparatus that delivers the pesticide active ingredient (nanosilver) and qualifies as a pesticide product subject to regulation by EPA.

#### Nanosilver is harmful to the natural environment

Although the literature is inconclusive with regard to silver nanoparticles' impact on human health, several studies have indicated that silver nanoparticles are highly cytotoxic *in vitro*. First, Braydich-Stolle et al., found that silver nanoparticles (15 and 100 nm) were more toxic than both molybdenum (30 nm) and aluminum nanoparticles (30 nm) to a mouse-derived spermatogonial stem cell line, inducing apoptotic cell death, impaired mitochondrial function, and increased plasma membrane leakage.<sup>ix</sup>

Second, a comparison of the cytotoxicity of silver (15, 100 nm), molybdenum (30, 150 nm), aluminum (30, 103 nm), iron oxide (30, 47 nm), manganese oxide (1-2  $\mu$ m) and tungsten (27  $\mu$ m) particles in an immortalized rat liver cell line *in vitro* showed that silver nanoparticles are the most toxic, causing membrane leakage and reduced mitochondrial functioning at lower doses. <sup>x</sup> Hussain et al. also showed that silver nanoparticles may cause cytotoxicity through generation of radical oxygen species leading to oxidative stress within cells.

Finally, in a study assessing neurological aspects of nanoparticle toxicity, Hussain et al. reported that silver nanoparticles (15 nm) were less acutely toxic than manganese oxide (40 nm) in a rat neuroendocrine cell line, but that the nanosilver still impaired

mitochondrial function and caused depletion of the neurotransmitter dopamine at high enough doses.<sup>xi</sup> Taken together, these studies indicate that the potential for harm to wildlife and ecosystems may be significant. Caution should be taken to prevent environmental releases until the toxicity of these particles is better understood, and they can be used safely.

In light of these concerns, EPA must evaluate the use of nanosilver in consumer products, and particularly the SilverCare<sup>TM</sup> Technology and The Sharper Image antimicrobial products using nanosilver, and appropriately regulate such products in accordance with FIFRA.

## Conclusion

As we begin to learn about the devastating effects of nanosilver on aquatic species, we must be vigilant in ensuring that these particles are not released into the environment. Products that are laundered or washed (e.g. socks and food containers) or washing machines that inject the particles directly into the water facilitate the release of nanosilver into the wastewater and eventually into the environment. While we applaud EPA's decision to subject Samsung's use of this pesticide to full toxicity testing requirements under FIFRA, because of the significant potential for serious environmental harm, EPA must conduct a comprehensive assessment of all products that use nanosilver as a pesticide. EPA's implementation of FIFRA is a nondiscretionary duty, and the Agency may not abdicate its responsibility in this regard. We believe that EPA will conclude, after full review and assessment, that the weight of the scientific evidence justifies either a prohibition or stringent restrictions on the use of nanosilver as a pesticide.

Respectfully,

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<sup>&</sup>lt;sup>i</sup> Kinney, J. EPA to regulate nanoscale silver used in washing machines to kill bacteria. Daily Environmental Reporter, No. 224, November 21, 2006. Page A-3.

<sup>&</sup>lt;sup>ii</sup> http://www.sharperimage.com/us/en/catalog/productdetails/sku\_ZN020

<sup>&</sup>lt;sup>iii</sup> Feb 8, 2006 and April 28, 2006.

http://web.archive.org/web/20060208021530/http://www.sharperimage.com/us/en/catalog/productdetails/sk u\_ZN020

<sup>iv</sup> "FresherLonger<sup>TM</sup> Miracle Food Storage Containers Are Naturally Anti-Germ, Anti-Mold & Anti-Fungus".

 $http://web.archive.org/web/20060208021530/http://www.sharperimage.com/us/en/catalog/productdetails/sku_ZN020$ 

<sup>v</sup> "FresherLonger<sup>™</sup> Miracle Food Storage Containers Are Naturally Anti-Germ, Anti-Mold & Anti-Fungus".

http://web.archive.org/web/20060208021530/http://www.sharperimage.com/us/en/catalog/productdetails/sk u\_ZN020

<sup>vi</sup> "SAMSUNG Laundry Featuring SilverCare<sup>TM</sup> Technology: Silver Ions Sanitize Clothing, All In An Energy-Saving Cold Water Wash" Samsung Press Release, 13 February 2006 <u>http://www.samsung.com/PressCenter/PressRelease/PressRelease.asp?seq=20060213\_0000233684</u> (20 November 2006).

<sup>vii</sup> Letter from California Department of Pesticide Regulation to TriTAC, dated February 22, 2006, available at http://www.tritac.org/letters.htm.

<sup>viii</sup> "SAMSUNG Laundry Featuring SilverCare<sup>™</sup> Technology: Silver Ions Sanitize Clothing, All In An Energy-Saving Cold Water Wash" Samsung Press Release, 13 February 2006 <u>http://www.samsung.com/PressCenter/PressRelease/PressRelease.asp?seq=20060213\_0000233684</u> (20 November 2006).

<sup>ix</sup> Braydich-Stolle L, Hussain S, Schlager JJ, Hoffman MC. In vitro cytoxicity of nanoparticles in mammalian germline stem cells. Toxicol Sci. 2005 Dec; 88(2): 412-9. Epub 2005 Jul 13.

<sup>x</sup> Hussain, S.M., K.L. Hess, J.M. Gearhart, K.T. Geiss, and J.J. Schlager. 2005. In vitro toxicity of nanoparticles in BRL 3A rat liver cells. Toxicology in Vitro. 19:975–983.

<sup>xi</sup> Hussain, S.M., A.K. Javorina, A.M. Schrand, H.M. Duhart, S.F. Ali, and J.J. Schlager. 2006. The interaction of manganese nanoparticles with PC-12 cells induces dopamine depletion. Toxicological Sciences. 92(2):456–463