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A Clear Commitment to America's Waters

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September 9, 2010

Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460
Via *Regulations.gov*

RE: Docket ID No. EPA–HQ–OPP-2009–1012; Registration of a new nanosilver active ingredient intended for use as a preservative in textile products

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on EPA's proposed conditional registration of a nanosilver active ingredient – HeiQ AGS-20 – that will be used as a preservative in textiles. NACWA represents the interests of nearly 300 public clean water agencies nationwide. After decades of controlling the discharge of toxic pollutants – including silver – to the sewer system, NACWA members are concerned that the increasing use of nanoscale silver in commercial and consumer products may have adverse effects on the wastewater treatment process and the environment. NACWA's comments below regarding the benefits of these products to the public and the assumption that they will not cause unreasonable adverse effects, though in reference to the HeiQ product and the current registration decision, apply equally to all nanosilver uses in textiles and the lack of available information on their potential environmental impacts given the unique properties of nanosilver.

Wastewater treatment plants have developed and implemented sophisticated pretreatment programs to prevent the discharge of toxic pollutants to the sewer system from industrial and commercial sources. Since certain forms of silver can be toxic to aquatic life and can prevent utilities from recycling their sludge or biosolids, pretreatment programs have been specifically designed to ensure that discharges of silver particles are minimized or eliminated. Treatment plants, however, do not have authority to control discharges of pollutants from domestic sources and the recent proliferation of consumer products containing silver jeopardizes the success of these pretreatment efforts.

The environmental assessments conducted for EPA's registration process, though in need of revision, are the only safeguard ensuring that pesticidal products will not have a negative impact on the environment. Unfortunately, since this conditional

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registration was not released in the *Federal Register*, many stakeholders, including many wastewater treatment plants that could be impacted by this product, will not have an opportunity to provide comments. NACWA only learned of the proposed action through an article in the trade press. Additional outreach to organizations that have commented on this issue in the past or that represent potentially impacted entities could have ensured a broader, more robust review process.

EPA is proposing to grant a conditional registration for HeiQ AGS-20, noting that not doing so would create an unfair market disadvantage because similar products are already being sold. According to the Agency's own records, similar silver-containing products were approved without knowing that the silver was at the nano-scale and without specifically assessing any unique risks posed by the nanosilver. While EPA is requiring the manufacturer, HeiQ, to conduct more studies, and the Agency is planning to ask for more data from those products already on the market, it is planning to allow the use of HeiQ AGS-20 while those studies are being conducted. EPA notes that use of this product is in the public interest and that use of the product during the period that the new data are being developed and reviewed by the Agency will not cause unreasonable adverse impacts.

Use of the pesticide is in the public interest

EPA believes that the use of the HeiQ nanosilver product should result in a lower potential environmental exposure to silver as compared to conventional silver-based pesticides. However, given that the proposed decision document also indicates that silver ionization is greater for nanoscale particles due to an increase in surface area, the supposition of a lower environmental silver exposure resulting from nanosilver products may be false. No studies have been provided comparing the environmental exposure resulting from conventional silver-based pesticides and nanosilver pesticides, so there are no data to support the hypothesis that the overall environmental exposure is lower with nanoscale silver products.

The consumer benefit highlighted is the prolonged antimicrobial activity of silver nanoparticles relative to other silver-based pesticides, but the studies provided were insufficient to effectively assess the leachability of the nanosilver and did not reflect the fact that the size of the silver particle can impact its properties. In fact, EPA's FIFRA Scientific Advisory Panel has noted that a particle's size substantially impacts its properties, such as rate and concentration of silver ion release and reactivity. NACWA believes EPA has insufficient information to declare that a particular nanosilver product has added value over other silver-based pesticides.

EPA's primary reason for the conditional approval appears to be its concerns over market fairness and the fact that other competing products are already on the market. NACWA believes that EPA should instead focus its efforts on existing products and make sure there are sufficient data to determine their potential impacts.

Use of the pesticide during the period that the newly required data is being developed and reviewed by the Agency will not cause unreasonable adverse effects

EPA supports its proposal for conditional registration by indicating that this type of approval is defensible as long as the new product is similar to products currently approved and that any differences that may exist are not likely to cause unreasonable adverse effect on the environment. None of the currently approved products, however, have provided the data necessary to conduct a sound environmental risk assessment for nanosilver. These products were approved for use before EPA's Scientific Advisory Panel recommended that the Agency handle nanosilver ingredients differently from conventional silver pesticides. NACWA understands that HeiQ submitted its application for registration in good faith, but the Agency's position on nanosilver has

subsequently changed. The conditional approval would be the first registration approval for a nanosilver pesticide and EPA must not circumvent the recommendations of its own Scientific Advisory Panel. If the Agency is concerned about creating an unfair market advantage, it should instead focus on getting the necessary information from those products that are already being sold rather than continuing to approve products on which it does not have sufficient information.

In terms of EPA's assessment of the potential for "unreasonable adverse effects", the environmental exposure for the conditional approval was calculated using the Down-the-Drain model and assumed a wastewater treatment removal efficiency of 88%. This removal rate was not based on the removal of nanosized materials and, therefore, such a high rate of removal cannot be assumed. The wastewater treatment process is typically far more effective at removing larger particles than smaller ones and so it is quite likely that there will be considerable pass through of small materials such as silver nanoparticles.

The Biotic Ligand Model (BLM) was used to evaluate the potential for in-stream toxicity from bioavailable silver. The predictions based on this model depend heavily on accurate receiving stream concentrations. These concentrations were derived from the Down-the Drain model output which was potentially flawed due to a likely overestimate of removal efficiency. The models' ouputs are directly linked to the validity of their inputs. The removal efficiency must be characterized based on nanosilver and not ionic silver.

Based on the model output, EPA made the determination that the level of environmental exposure was unlikely to cause environmental harm. However, EPA recognizes that neither model considers the additive effect of other silver nanoparticles or silver containing products on the market. In addition, the *Daphnia magna* toxicity values which were used to evaluate the potential for in-stream toxicity, were based on ionic silver. This is problematic as the FIFRA Scientific Advisory Panel stated: "...nanomaterials can deliver ions directly to specific tissues, cell membranes and inside cells – places where other forms of silver cannot reach. Therefore, the hazard profile of silver nanomaterials may differ from other forms of silver." This, coupled with the EPA statement that "...existing data seem to indicate that [nanosilver's] effects are different and/or more severe than for silver", does not corroborate EPA's expectation of "no unreasonable adverse effects" associated with approval for this product.

Additional Comments

From a wastewater treatment perspective, the conditional approval of another nanosilver product is discouraging. Wastewater utilities have been working diligently to reduce the input of silver into their wastestream in order to limit its presence in biosolids and wastewater effluent. Though strict pretreatment programs can limit the amount of silver entering the wastestream, treatment plants do not have the authority or capability to regulate residential waste which is likely to be a large contributor of nanosilver materials.

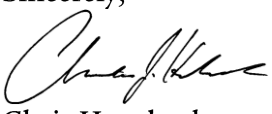
In addition, the work by Choi and Hu (2008) and Choi et al. (2008), which indicates that silver nanoparticles can have an increased inhibitory effect on the bacterial community vital to the wastewater nutrient removal process, is very concerning. With strict nutrient limitations imposed by National Pollutant Discharge Elimination System (NPDES) permits, there is little tolerance for even minor upsets to the microbial community present within the wastewater treatment plants. In addition to the other data requirements, EPA must require any nanosilver pesticide product to be evaluated to assess its potential for nitrification inhibition at the wastewater treatment plant. In addition, it is not clear if a measure of removal efficiency during the wastewater treatment process is a component of the Tier 2 study requirements. Information on treatability is

vital to characterizing environmental exposure in the Down-the-Drain model and must be a requirement of any Tier 2 data collection efforts.

It is imperative that EPA consider this approval with great caution. Silver is one of the most toxic heavy metals and any decision that may result in its increased environmental exposure must be made with the right scientific data in hand. As far as NACWA has been able to determine, this is not a scenario in which conditional approval is being granted pending the approval of a few additional studies. In this case, there are no current data that can be used to support a conclusion of "no unreasonable adverse effects" for the unique properties of nanosilver. EPA should instead work, to the extent of its authority, to limit the use of the other nanosilver products that have been unknowingly registered until the necessary data are provided.

Again, NACWA appreciates the opportunity to comment on this conditional approval and the Agency's approach to assessing nanosilver products more broadly. NACWA feels strongly that inadequate public notice has been provided and that insufficient data have been collected to support EPA's approval at this time. Please contact me at *chornback@nacwa.org* or 202/833-9106 if you would like to discuss these comments further.

Sincerely,



Chris Hornback
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REFERENCES

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