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Office of Pesticide Programs
Environmental Protection Agency
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Comments on Registration of "HeiQ AGS-20," a new nanosilver active ingredient intended for use as a preservative in textile products

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In August 2010, the Environmental Protection Agency (EPA) announced that it is considering allowing the Swiss company HeiQ Materials Ag (HeiQ) to come into the U.S. market with a new nanosilver pesticide and textile preservative, HeiQ AGS-20. This textile coating would be infused in sportswear and marketed as a control for the odor of frequently used clothing.

The agency's willingness to introduce this product on the American market is simply baffling. Even as it proposes to grant the Swiss nanosilver coating access to the U.S. market for the next 4 years under a conditional registration, the agency expresses many qualms about its potential to harm people and the environment. The proposal acknowledges bluntly that EPA "lacks information to conduct a complete assessment of the potential risks to human health and the environmental associated with the use of AGS-20," that there is "considerable uncertainty about the risk assessment" and that "more extensive product chemistry, toxicology, exposure, and environmental data are necessary to… provide an accurate assessment of the risks" (EPA 2010a).

Environmental Working Group (EWG), a non-profit research and advocacy organization that focuses on public health and environmental science, opposes EPA's plan for conditional registration of HeiQ AGS-20 and asks the agency not to approve this nanosilver antimicrobial for consumer products until its maker produces all the data EPA requires for regulation of antimicrobials (EPA 2010b) and until EPA evaluation of these data determines that the product is safe for people and the environment.

Nanosilver consists of manufactured, nanometer-scale particles of silver. According to research studies, these particles can be toxic to cells that develop into eggs or sperm in mammals (Braydich-Stolle 2005, Braydich-Stolle 2010). Recent studies suggest that nanoparticles may penetrate the skin, cross cell membranes to reach the interior of cells and enter the brain through the blood-brain barrier (Jordan 2010). There is also evidence that nanomaterials may be toxic when inhaled, especially for people with pre-existing respiratory diseases such as asthma (Bonner 2010).

Through EWG expertise in chemical contamination, we are keenly aware of the possible risks of nanomaterials to human health. A growing body of scientific literature indicates that nanoparticles would likely have unexpected toxicity properties that cannot be fully predicted from the study of the non-nano forms of the same substances (Faunce 2010; FIFRA SAP 2010; Jordan 2010).

Previously, EPA has approved at least four nanosilver-based products "without knowledge that these products contained nanoscale silver and without specifically assessing any potential risks that might be associated with the specific nanoparticles contained in those products" (EPA 2010a). In contrast, for HeiQ AGS-20 EPA has the full knowledge that it is a nanomaterial pesticide and thus the agency should require a complete dataset submission for its registration.

Many companies infuse sportswear with antimicrobial pesticides, advertising them as effective in controlling the smell of athletic clothing (HeiQ 2010). The Swiss company HeiQ Materials Ag is not the first to propose treating textiles with silver formulations to prevent bacterial growth and a number of textile companies are now researching such an application (Kulthong 2010). It is true that nanosilver can kill bacteria on contact (Sotiriou 2010) but washing clothes regularly works just as well. Overall, compared to a standard washing, the hygiene advantages of nanosilver-treated articles are slim and may be temporary (Benn 2008). On the other hand, disadvantages are obvious: people of all ages, including children, would be exposed to a new nanosilver formulation while wearing treated clothes and after nanosilver leached into the washing machine laundry load and onto other clothing. Meanwhile, wash water would carry nanosilver particles into the general water supply and contaminate groundwaters as well as animal and plant habitat (Geranio 2009).

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") requires all pesticides used in the U.S. to be registered with the EPA after their makers submit environmental, health, and safety data confirming that the substance would not cause "unreasonable adverse effects on the environment" (EPA 2010c).

Silver itself (in the form of naturally occurring silver ions, a form far different from manufactured, nano-sized particles of silver) is a registered pesticide that EPA considers "highly toxic to fish, aquatic invertebrates and estuarine organisms" (EPA 1991). Studies of nanosilver indicate that its toxicity can be more severe and quite different from the ionic form of silver previously tested (EPA 2010a; FIFRA SAP 2010).

In a Pesticide Program Dialogue committee meeting in April 2010, William Jordan, senior policy advisor to the EPA Office of Pesticide Programs, said that nanoscale materials would be reviewed separately from their non-nano form. "When an active or an inert ingredient contains a nanoscale material, it would be presumptively considered a new active or a new inert ingredient even if there is a conventionally-sized active ingredient already in a registered product," he said (EPA 2010c; Jordan 2010). EWG strongly supports Mr. Jordan's approach as a key step towards protecting human and environmental health and significant advance over EPA's earlier position on nanoscale substances (EPA 2008). The FIFRA Scientific Advisory Panel on conducting risk assessments for nanosilver pesticides has also recommended separate treatment of nanomaterials and their bulk-sized counterparts (FIFRA SAP 2010).

The present proposal by EPA's Office of Pesticide Programs to grant the Swiss nanosilver textile coating a four-year "conditional" approval would undermine the agency's recent progress and set a dangerous precedent. EWG urges that EPA:

- Deny registration to the Swiss product until the agency has received all necessary data and has fully assessed risks to human health and the environment;
- Assess cumulative exposures and risks to human health and the environment considering all nanosilver based products on the market;
- Require all nanosilver pesticide registrants to address data gaps on the potential toxicity of these materials and produce full dataset the agency requires for the standard process of pesticide registration.

EWG has signed a letter drafted by the Natural Resources Defense Council that characterizes conditional registrations of pesticide products as "a way for registrants to gain rapid market access while delaying, or even avoiding the data requirements for product registration" (NRDC 2010).

In the case of AGS-20, EPA has met neither of the two statutory requirements for conditional pesticide registration under FIFRA – a determination that the use of the pesticide during the period of conditional registration "will not cause any unreasonable adverse effect on the environment" and "that use of the pesticide is in the public interest."

As the NRDC letter points out, the agency cannot show that a decision to allow the Swiss textile coating on the market is in the public interest. To the contrary:

- EPA lacks critical data needed to assess the safety of AGS-20 (EPA 2010a).

- Without such data, EPA cannot determine that the product will not cause an "unreasonable adverse effect to the environment." The use of nanosilver antimicrobials in textiles will result in releases to the environment from manufacturing and from wastewater treatment plant effluent laden with nanosilver from home laundry wash (Benn 2008; Geranio 2009). Such discharges may cause harm to beneficial microbes, aquatic life, and other unintended targets (Liang 2010). EPA has not evaluated the risks of these impacts.

- EPA has not fully evaluated risks to exposed consumers, including children who mouth nanosilver-infused clothing.

- EPA has allowed thousands of pesticides to remain "conditionally" registered for longer than a decade, and in some cases, up to two decades. (NRDC 2010). Given this history, one must question whether a four-year "conditional" registration would be extended indefinitely.

EWG opposes EPA's conditional registration of the nanosilver AGS-20 antimicrobial for three other reasons:

1. EPA puts public health at unnecessary risk by approving nanomaterials for use in consumer products in the absence of the basic health and safety data the agency requires for antimicrobials (EPA 2010b). Nanomaterials can be uniquely toxic; EPA cannot ensure that health and the environment will be protected until it evaluates a full set of chemistry, environmental fate, and toxicity data.

Importantly, instead of providing "economic" and "consumer benefits" and advancing "conservation of the environment" (EPA 2010a), marketing of this new nanosilver product would promote the overuse of antimicrobials in consumer products in general, a public health concern identified by authoritative bodies such as the American Academy of Microbiology (AAM 2009). As EWG has advised EPA in comments on the agency's draft antimicrobial rule (EWG 2009), the overuse of antimicrobial products may lead to wide-ranging problems, including environmental pollution, toxicity to ecosystems, antimicrobial resistance and other potential human health risks (Aiello 2007; Focazio 2008).

Conditional approval for a pesticide requires that such a registration be in the public interest. EPA argues that this condition is met because the Swiss product can maintain "efficacy longer than other silver active ingredients due to an expected gradual and controlled release of silver" (EPA 2010a). However, EPA did not assess the negative public health impact of promoting widespread antimicrobial use.

EPA also justifies proposed conditional registration on the grounds that "insufficient time has elapsed from the point at which EPA determined and informed HeiQ of the data requirements needed to assess HeiQ's application for HeiQ to have generated the data" (EPA 2010a). Yet pesticide data requirements are not new; they are well known to the pesticide manufacturers (EPA 2010d). The FIFRA Scientific Advisory Panel and EPA's own reviews have determined that the toxicity of nanosilver pesticides should be addressed in their nanoparticle form (EPA 2010c; FIFRA SAP 2010). In this case, the manufacturer did not provide EPA data on its specific nanomaterial and instead argued that it is similar to other silver-based antimicrobials. This assertion does not relieve HeiQ of the responsibility to generate and produce all the data EPA needs for an adequate assessment. Clearly, a conditional registration cannot be granted based on the argument that registrant needs more time to test its product.

2. Risks to human health and the environment will be defined by cumulative exposures to HeiQ AGS-20 and other nanosilver-containing consumer products already on the market. Ignoring cumulative exposures, as EPA proposed with the AGS-20 conditional approval, could jeopardize human health.

According to the analysis from the International Center for Technology Assessment, over 260 consumer products currently on the U.S. market may contain nanosilver (CTA 2008). In its proposal for conditional registration of HeiQ AGS-20, EPA has argued that the presence of other

nanosilver products on the market means that this new pesticide would not significantly increase the risk of unreasonable adverse effects on the environment. Additionally, in laying out its rationale for approval, EPA estimated that people's exposures to the AGS-20 from treated fabrics alone would be below the levels of silver where adverse effects may be observed according to currently available studies (EPA 2010). Unfortunately, total consumer exposures to nanosilver are far higher than EPA's estimates for the AGS-20 alone. Additionally, in the absence of essential data, mammalian toxicity of nanosilver is still inadequately understood and may well be much higher than that of silver ions. Protection of human health can be assured only if the agency evaluates cumulative exposures and risks.

EWG urges EPA to conduct a full human and environmental toxicity analysis of the nanosilver products currently on the market and the cumulative exposure that vulnerable populations, such as children and pregnant women, may receive from all sources. We also advise the agency to carry out a life cycle analysis of nanosilver products that would carefully consider environmental fate and transportation of these antimicrobial ingredients from home applications and consumer products to wastewater plants and the receiving water bodies. Finally, in addition to data requirements laid out in the Appendix A of the current proposal (EPA 2010a), EPA should require manufacturers to conduct ongoing environmental monitoring that would inform the agency and the scientific community about the extent of nanosilver contamination in the environment that may result from the wastewater release of these pesticides.

3. Nanosilver pesticide registrants, including the HeiQ company and past registrants of similar approved products, should addressed outstanding data gaps on the potential toxicity of these materials. Until these gaps are filled, EPA cannot ensure that nanoparticle antimicrobials are safe for widespread use in consumer products.

In its proposal EPA has outlined the extensive testing that must be done to carry out an adequate risk assessment of nanosilver pesticides (EPA 2010a). Major data gaps in the limited currently available information preclude any reliable risk characterization. Most importantly, the registrant has not completed tests of environmental persistence and product breakdown, information that EPA considers "fundamental" for any risk assessment. Thus, a conditional registration for this pesticide would be premature and unwise from both a science and a policy perspective.

Human and environmental exposure to nanosilver from AGS-20 products can occur in three forms, "AGS-20 nanosilver-silica composite particles, silver nanoparticles that break away from the composite particle and silver ions released from the treated textiles" (EPA 2010a). There remains a significant data gap in both the release of AGS-20 particles from treated fabric and the release of silver nanoparticles from the AGS-20 particles. Strikingly, little to no data has been submitted on the safety of the silver nanoparticles utilized in the AGS-20 substance.

EWG urges EPA to require all nanosilver pesticide manufacturers to address these data gaps expeditiously, and prior to any marketing of new nanosilver products in the U.S. This testing should be done with the actual nanomaterials that are applied to consumer products. EWG supports FIFRA Science Advisory Panel recommendations that "the potential environmental

impact of nanosilver products should be carefully evaluated based on product life cycle" and that toxicity tests should "simulate realistic use of products and potential nanosilver release with subsequent quantitative life cycle assessment and risk assessment" (FIFRA SAP 2010). Due to the potential for high toxicity of various product components that may be released in use or in disposal of nanosilver-treated fabrics and clothing, EPA should understand the health consequences of these releases prior to approving nanosilver pesticides.

In order to carry out its mission to protect human health and the environment, EPA should publish a mandatory data call to collect basic information on the presence of nanometer sized particles in all currently registered pesticides, including nanosilver-based antimicrobial products approved in advance of AGS-20 (EPA 2010a). Assessing human health and environmental impact will be greatly aided once EPA has an understanding of the composition details of currently registered products. All products containing nanomaterials should be required to meet the safety standard.

Conclusion

The gaps in health and safety data on nanosilver pesticides summarized in EPA's assessment of HeiQ AGS-20 indicate significant uncertainties about the safety of such products and the possibility of future adverse effects from new nanoscale materials that could be placed on the market without adequate evaluation. While EPA's stated intent of using the data requirement for HeiQ AGS-20 as a good starting point for all future nanomaterial products, these requirements must be meet *before* a product is sold to consumers, not after.

Sincerely,

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