



NATURAL RESOURCES DEFENSE COUNCIL  
THE EARTH'S BEST DEFENSE

September 10, 2010

Comments from the  
NATURAL RESOURCES DEFENSE COUNCIL  
on the proposed conditional registration of a pesticide product  
HeiQ AGS-20, containing nanosilver

Docket ID # EPA-HQ-OPP-2009-1012

**I. Background**

EPA is proposing to conditionally register a pesticide product containing nanosilver as a new active ingredient for a period of 4 years. The antimicrobial pesticide product, HeiQ AGS-20, is a silver-based product that is proposed for use as a preservative for textiles. As a condition of registration, EPA is proposing to require product chemistry, toxicology, exposure, and environmental data. The data requirements are based on the regulations governing the registration of pesticides and on a November 2009, independent consultation EPA held with the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) Scientific Advisory Panel (SAP). In its final report, the SAP addressed a number of questions associated with assessing the hazard of and exposure to nanosilver and other nanoscale metal-based pesticides.<sup>1</sup>

The Agency states that it “will evaluate these data as they are submitted during the period of the conditional registration to confirm the product will not cause unreasonable adverse effects to human health and the environment.” (Decision Doc at 4)

On August 12, 2010 EPA issued a 36-page Proposed Decision Document for the Registration of HeiQ AGS-20 as a Materials Preservative in Textiles which is available in the docket as ID# EPA-HQ-OPP-2009-1012-0014. Unless otherwise indicated, references are to this Decision Document.

In its Proposed Decision Document, EPA determined that “the nanosilver active ingredient in the product differed from currently registered silver-based antimicrobial products” and thus, “EPA

reclassified the application under the PRIA [Pesticide Registration Improvement Act] as one involving a ‘New Active Ingredient Registration’” (Decision Doc at 4).

## **II. Summary of comments**

NRDC opposes registration of nanosilver, because its use as an antimicrobial in textiles may cause “unreasonable adverse effects on the environment.”<sup>2</sup> Specifically, its use will result in human exposures and environmental releases which are likely to cause harm to beneficial microbes and other unintended targets; the impacts of these risks have not been evaluated. EPA acknowledges that it “lacks information to conduct a complete assessment of the potential risks to human health and the environment associated with the use of AGS-20,” and so EPA determined that “more extensive product chemistry, toxicology, exposure, and environmental data are necessary.” (Decision Doc at 3, 36, Appendix A). EPA therefore may not lawfully register this pesticide. Regrettably, despite this extensive and significant lack of data, rather than denying the registration until the data is submitted and reviewed, EPA is proposing to require these studies as a condition of registration. (Decision Doc at 3).

NRDC is opposed to the conditional registration. In general, we are concerned that conditional registrations, representing two-thirds of current product registrations, have been overused, possibly as a way for registrants to gain rapid market access while delaying, or even avoiding, the data requirements for product registration. But more specifically, EPA has failed to show that AGS-20 satisfies the conditions under which a conditional registration may be granted. First, the registrant for AGS-20 has failed to submit data that EPA regulations specifically identify as required to register an antimicrobial pesticide. These data requirements are clearly laid out in the Code of Federal Regulations. The registrant does not need and is not entitled to an additional period of time to generate the data because these are not supplemental requirements – they have always been required by EPA. Second, EPA has failed to show that registering it will not cause any unreasonable adverse effect on the environment. These uses, in addition to offering no measurable or documented benefits to the public, are likely to lead to occupational inhalation exposures, incidental dermal and oral exposure to children wearing treated clothing, and releases of silver ions to the environment. Silver ions are well-known to have non-specific microbe-killing activity, threatening beneficial microbes on our bodies as well as in the environment. Third, EPA has failed to show that conditional registration of AGS-20 is in the public interest. Therefore, the proposed registration of AGS-20 is a misuse of EPA’s authority and is likely to lead to unsafe exposures to consumers and the environment. Instead of giving AGS-20 market access, EPA should be reining in companies that are marketing unregistered and therefore illegal nanosilver pesticide products.

## **III. Summary of silver toxicity and regulation: need for stringent registration review of nanosilver**

Silver metal is a well-recognized non-specific antimicrobial metal. Silver ions (positively charged atoms, Ag<sup>+</sup>) are more toxic to aquatic organisms than any other metal except mercury.<sup>3</sup> Silver is toxic, persistent in the environment, and has the potential to bioaccumulate in ocean

plants at concentrations 10,000 to 70,000 times higher than in the surrounding sea water.<sup>4</sup> Its historical use in developing film for traditional photography proved that the release of silver into the waste stream is deadly for aquatic biota. Silver is acutely toxic to aquatic organisms at exquisitely low concentrations, as low as 50 ng/L (parts per trillion, ppt); a study in fish embryos reported toxicity down to 10 ng/L.<sup>5</sup> Because of its extreme toxicity to aquatic organisms, discharges of silver effluent into lakes, streams, ponds, or any public water is subject to National Pollutant Discharge Elimination System permit restrictions, and any water that has been treated with silver pesticide cannot be discharged into the sewage systems without first notifying the sewage treatment authorities.<sup>6</sup>

EPA's 1993 Reregistration Eligibility Decision (RED) for silver notes that in humans when it is inhaled or ingested, it can be absorbed from the lungs and the gastrointestinal tract into the blood stream, where it causes a permanent skin discoloring condition called argyria.<sup>7 8</sup> The oral reference dose, considered the acceptable daily intake limit over a lifetime, established by EPA in 1991 for silver is 0.005 mg/kg/day.

Nanosilver, or silver nanoparticles, are made up of clusters of silver ions. Silver nanoparticles are intentionally engineered to release silver ions, which is the mechanism of their enhanced microbe-killing activity. In addition to releasing more antibacterial ions, silver nanoparticles appear to be able to penetrate into cells better than silver, or possibly, to deliver ions directly into cells. These are believed to be the properties that make nanosilver a much more efficient antimicrobial than silver, and much more toxic.<sup>9</sup> In cultured mouse sperm stem cells, a 48 hr treatment of nanosilver (15 nm diameter) was 45-fold more toxic than silver carbonate (EC50 of 8.75 v 408 ug/ml) in a concentration-dependent manner; nanosilver was the most toxic of the nanomaterials tested, and drastically reduced mitochondrial function and cell viability.<sup>10</sup> The Scientific Advisory Panel (SAP) in its 2010 report noted several major differences between silver and nanosilver that were likely to result in a distinct hazard profile for nanosilver. However, the SAP noted that there are no studies that are definitive regarding a comparison of silver and nanosilver toxicity, and more research is required.<sup>11</sup> The SAP report therefore provides an argument against the actions EPA is proposing here, to put nanosilver on the market essentially untested, with an inadequate hazard database, while knowing that it is likely to be more hazardous than silver.

#### **IV. Specific comments**

##### **A. EPA has not satisfied the requirements for granting AGS-20 a conditional registration**

FIFRA allows EPA to grant conditional registrations for active ingredients not contained in currently registered pesticides

for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the

condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.<sup>12</sup>

EPA proposes to grant the conditional registration for AGS-20 claiming that insufficient time has elapsed for the generation of data since the requirement for that data was imposed; 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; and use of the pesticide is in the public interest. (Decision Doc at 3) However, EPA has misapplied the standard and failed to make the requisite showing to grant a conditional registration.

*1) The registrant has had sufficient time to generate and submit required data*

FIFRA allows EPA to grant conditional registrations of active ingredients not contained in any currently registered pesticides to allow registrants to generate and submit required data.<sup>13</sup> However, that data can only be lacking “because a period reasonably sufficient for generation of the data has not elapsed since the Administrator *first imposed* the data requirement.” (emphasis added). As further explained in the regulations

EPA will not approve an application for conditional registration of a pesticide containing an active ingredient not contained in any currently registered product unless data required by this part are available for EPA to review except for:

- (i) Those data for which the requirement has been waived.
- (ii) Those data for which the requirement was imposed so recently that the applicant has not had sufficient time to produce the data.<sup>14</sup>

EPA regulations specify the types of data and studies that are required for EPA to evaluate the risks or benefits of a product having a particular use pattern.<sup>15</sup> Some studies are absolutely required, such as genetic toxicity studies, which are used to screen chemicals for mutagenic or carcinogenic potential.<sup>16</sup>

Other studies are conditionally required.<sup>17</sup> If certain conditions apply, then the conditionally required studies must also be submitted. The burden is on applicants to evaluate those conditions “to determine whether or not conditionally required data must be submitted as indicated by the conditions and criteria specified” in the regulations.<sup>18</sup> For example, a 90-day inhalation toxicity (rat) study is required if use of the pesticide product may result in repeated inhalation exposure at

a concentration likely to be toxic.<sup>19</sup> A 21-day dermal toxicity (rat) study is required if the intended use of the pesticide product is expected to result in human exposure via skin contact.<sup>20</sup>

In this case, EPA proposes conditionally registering AGS-20 and identifies a list several pages long of studies that the registrant will need to submit during the conditional period. EPA explains that the conditional registration is appropriate because it only recently reached a position about what types of data are needed to evaluate the potential risks to humans and to the environment.<sup>21</sup>

EPA has misapplied its authority to grant conditional registrations under FIFRA. Only when a data requirement is “first imposed” so recently that a registrant is unable to generate the data in time for the registration application may EPA grant a conditional registration. For example, there are situations where EPA may require additional information be provided because those data specified in the regulations are insufficient to permit EPA to evaluate the product.<sup>22</sup> When that new information is requested, a registrant should be given sufficient time to generate the data. That, however, is not the case here. In many instances, this application is completely missing data that are specifically required by the regulations and which are not new requirements.

For example, genetic toxicity tests are absolutely required under 40 CFR §161.340(a). The Decision Document indicates that there are “No Data” from genetic toxicity tests, which are used to determine whether the product is a potential mutagen or carcinogen. These tests have been required since the regulations were first established in 1984.<sup>23</sup> As such, all registrants have had over 25 years of notice that EPA has imposed this requirement, which is more than “sufficient for generation of the data...”<sup>24</sup> It is a violation of FIFRA to allow registration of this product in the complete absence of these required data.

The missing conditionally required data also mean that the conditional registration cannot be granted. For example, the application is missing, *inter alia*, two conditionally required studies: 90-day inhalation toxicity data and 21-day dermal toxicity data. The applicant should have known that these conditionally required studies must be completed and submitted based on the notes in the regulations.<sup>25 26</sup> First, the formulation of AGS-20 as a powder will cause occupational inhalation exposures during handling during textile treatment and during manufacturing of clothing. It is reasonably foreseeable that inhalation exposure would occur (the condition requiring a 90-day inhalation toxicity test), and the registrant should have submitted that data. Second, the use of this product on clothing means that consumer dermal exposures could occur while wearing treated textiles. Again, this is a reasonably foreseeable occurrence, and should have been considered by the registrant. The registrant has the burden of identifying that these conditional data must be submitted. These are not new data requirements. The registrant’s failure to provide these data in the application means the registration cannot be granted.

2) *AGS-20 may cause “unreasonable adverse effects on the environment”*

To grant a conditional registration, EPA must also determine that “use of the pesticide during such period will not cause any unreasonable adverse effect on the environment.” 7 U.S.C.

§136a(c)(7)(C). Such a determination includes any “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of a pesticide.” 7 U.S.C. §136(bb). EPA cannot make such a determination for AGS-20.

For HeiQ AGS-20 products, EPA has already properly determined that both dermal and incidental oral exposures will occur to consumers, and particularly children, through wearing treated clothing and mouthing of treated clothing (Decision Doc, App A at 10). NRDC agrees that people wearing treated clothing will have dermal contact with the chemical, and that some mouthing of the material is highly likely to occur with infants and young children who come into contact with the clothing, either on themselves or a parent, sibling, etc. The special considerations of the impact of these exposures on children and infants must be incorporated into EPA’s assessment of these unique materials. Because EPA has failed to consider or evaluate these exposures, the Agency may not make the required safety finding under FIFRA.

When considering life-stage related sensitivities to nanoparticle toxicity, the elderly also represent a vulnerable subpopulation. The EPA-funded study by Gordon et al (2008) found a significant difference in the toxicity of inhaled zinc nanoparticles on young versus old mice which varied depending on the inbred strain of mice. The old (8-12 months) mice were more sensitive than the young (2-3 months) adult mice in three inbred strains, but the opposite was true in the BtBr strain.<sup>27</sup> These data suggest that age-related sensitivity and genetics may be a very significant factor in the toxicity of inhaled metal nanoparticles like zinc and silver, which EPA unlawfully failed to consider in its assessment of HeiQ AGS-20.<sup>28</sup>

Aggregation of nanosilver is likely to be a significant influence on toxicity, which the SAP noted in its report (SAP at 10). An EPA funded study by researchers from the New York University Nelson Institute of Environmental Medicine (Gordon et al, 2008) exploring the role of particle agglomeration on nanoparticle toxicity reported that particle composition as well as size affected toxic properties.<sup>29</sup> The researchers tested inbred BALB/c mice exposed by inhalation. Inhaled freshly generated carbon nanoparticles (11-60 nm range) produced much greater lung inflammation than the larger-sized aged carbon nanoparticles (150-250 nm). Under identical test conditions, copper and zinc nanoparticles showed less of a difference between fresh and aged, but both metals produced 3-fold more inflammation and lung injury (measured by protein) than carbon nanoparticles, demonstrating particular concerns with the toxicity of agglomerated metal-based nanoparticles. These effects seemed to override size differences, because even the larger-sized aged and agglomerated copper nanoparticles (approximately 200 nm diameter) produced significantly more lung inflammation than freshly generated carbon nanoparticles of a comparatively smaller size (11-60 nm). This demonstrates the exquisite immunotoxicity potential of metal-based nanoparticles like copper, zinc, and silver. Other published studies by independent scientists have also identified inflammation and immunotoxicity as a very sensitive, possibly the most sensitive endpoint of toxicity for metal-based nanomaterials including nanosilver.<sup>30</sup> EPA unlawfully failed to consider immunotoxicity in its assessment of HeiQ AGS-20, and therefore may not make the required safety finding under FIFRA.

*3) Use of the pesticide is not in the public’s interest.*

In order to grant a conditional registration, EPA must also determine that use of the pesticide is in the public interest.<sup>31</sup> EPA has sided with the registrant that the registration of this product benefits the public based on four points: 1) conservation of the environment, 2) consumer benefits, 3) market equity and international trade, and 4) innovation. (Decision Doc 28-30) EPA provides no actual economic calculations or numerical data to support its finding for any of these points. Rather, the determination is based on supposition, conjecture, untested assumptions, and unproven claims. EPA also entirely ignores the public interest in not registering AGS-20 before its safety has been established, as required by law.

For the first claim, EPA notes that silver is already a registered pesticide, and that compared with normal-scale silver, the volume of silver in HeiQ's product is reduced. EPA argues that by making nanosilver available, less overall silver (by mass) will be released into the environment (Decision Doc at 28-29). This argument is false logic, a red herring, since nanosilver is much more potent (effective) – that is, less nanosilver kills more microbes. While AGS-20 may possibly lead to a reduction in the overall mass of silver released into the environment, its killing potential is greater and therefore the potential for environmental damage and non-target impacts is greater. In fact, the SAP noted in its 2010 report that the rate and concentration of deadly silver ions released from nanosilver is different and will likely affect the acute or chronic toxicity of nanosilver compared with silver.<sup>32</sup> The SAP referenced data showing that nanosilver, but not silver, can penetrate cell membranes and deliver toxic ions directly inside of cells and that this may be its mechanism for killing microbes so effectively.<sup>33</sup> The SAP also noted that “when compared as a function of silver ion concentration, the toxicity of silver nanoparticles appeared to be much higher than that of silver nitrate.”<sup>34</sup> Moreover, the SAP noted that because of these differences in chemical properties, there are likely to be differences in exposure and environmental fate of nanosilver that should be considered.<sup>35</sup>

The second claim of consumer benefits is also false logic. EPA claims that consumers will benefit because the nanosilver product is a more effective antimicrobial, and therefore consumers owning textiles treated with the product will enjoy more durable, longer-lasting antimicrobial protection. But, EPA has not explained why consumers need antimicrobial textiles. In fact, the textiles that nanosilver products are being used in are mostly unnecessary and lead to potentially harmful exposures. For example, sports clothing that may stink less, camping clothing that may stink less, and towels and bed sheets that are touted to have less germs. This is a marketing campaign that targets consumers who mistakenly believe all microbes are harmful – not unlike the pre-1970s advertising campaigns of the leaded paint industry that marketed deadly leaded paints for children's toys and furniture by associating brighter colors and whiter whites with cleanliness and better health.<sup>36</sup> In fact, our bodies are covered with beneficial bacteria and microbes – little “germs” that eat away our dead hair and skin, help us digest food, and fight off other bacteria.

The third claim is market equity. EPA makes two arguments. First, it argues that the Agency may conditionally register pesticides that are identical or substantially similar to currently registered pesticides or pesticides that differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment (Decision Doc at 29-30). This is inapposite. Compared with silver, nanosilver releases more ions and is therefore more toxic, more biologically active, more deadly to microbes, and more persistent in the environment

(Decision Doc at 28). Second, EPA argues that other products that are on the market were registered as silver, but are now known to contain nanosilver. EPA states that although the registrations were approved without EPA's knowledge that nanosilver was a component of the product, it would give HeiQ an unfair disadvantage to deny its registration while its competitors are already on the market. This has nothing to do with the public interest; it goes only to the private financial interest of the registrant. EPA should not allow *any* nanosilver pesticide to be in commercial products. It is an off-label use, and therefore illegal. EPA has stated that nanosilver is not silver, and therefore it must be reviewed and registered under FIFRA separately from silver.<sup>37</sup> William Jordan, Senior Policy Advisor, OPP, made clear at the April, 2010 public meeting of the Pesticide Program Dialogue Committee EPA's intention to issue a Federal Register notice clarifying the Agency's position that the presence of a nanoscale material is reportable under FIFRA Section 6(a)(2) and that an active or inert ingredient would be considered "new" if it is a nanoscale material.<sup>38</sup> The SAP also voiced its scientific opinion that the toxic profile of nanosilver is likely to differ from silver in many significant ways, including rate of ion release, environmental fate, chemical reactivity, agglomeration, and distribution in biological tissues.<sup>39</sup> EPA should be issuing fines for violation of FIFRA to those companies that keep their products on the market without a lawful registration, not giving companies a free pass.

Innovation is EPA's fourth argument that the registration of AGS-20 is in the public's interest. EPA bemoans the high costs of regulatory requirements, including new data generation, on the registrants and even frets that these regulatory costs may "discourage technology providers from pursuing the development of beneficial new applications of nanotechnology in the field of pesticides." (Decision Doc at 30). This argument is presented without any supporting data, or even "guesstimates" of the actual costs and benefits of this "innovative" technology. Pesticides are inherently hazardous. In passing FIFRA, Congress mandated that all pesticides go through a rigorous pre-market chemical risk assessment and product registration process, which must be repeated every fifteen years. The costs of research and development should include the development of statutorily mandated pre-market hazard data. EPA must apply and enforce these requirements under FIFRA.

The conditional registration of AGS-20 is not in the public interest. It provides no measurable medical or health benefits to consumers, but puts them in harm's way. There seems to be little doubt, including with EPA, that workers will inhale the powdered pesticide during manufacturing processes, that consumers will come in direct contact with the pesticide while wearing treated clothing, and that children have a high likelihood of ingesting the pesticide while mouthing the clothing in addition to direct dermal contact. Because the proposed application is to treat textiles that consumers will come into direct contact with, exposure will be unavoidable. The potential harm from such contact is poorly understood and untested, which is a direct violation of FIFRA requiring that safety findings be made. Moreover, release of the silver ions into the water waste stream from nanosilver-impregnated clothing through routine washing will pose a threat to aquatic ecosystems, aquatic food webs where bioaccumulation may occur, and embryonic fish that may be killed by even ppt levels of silver ions. It is also possible that nanosilver may impair the beneficial microbial systems that are used to treat sewage, leaving waste water plant effluent highly contaminated and unsafe. These harms are more than speculative. They can be reasonably presumed to occur in at least some individuals and

ecosystems, based on what we know about silver toxicity and about the strong likelihood that nanosilver is more harmful than silver to non-target aquatic species and beneficial microbes.<sup>40</sup>

### **B. Time to generate data should not be time on the market**

In addition to violating the law, EPA's proposed conditional registration is also irresponsible. With the amount and the importance of the data that EPA is requiring (see Decision Doc, Appendix A for full list), it is unacceptable that EPA has given this product market access, conditionally or otherwise. EPA recognizes the inherent hazards of nanomaterials generally, and nanosilver specifically, commenting that the inhalation of other nanoparticles has led to pulmonary fibrosis, that workers could be exposed during handling of the powder, and consumers will be exposed dermally through wearing treated clothing. EPA comments that "there is a potential for children's incidental oral exposure to AGS-20 during the wearing and mouthing of treated clothing," triggering the requirement for reproductive/developmental studies (Decision Doc, Appendix A at 10).

In addition, EPA does not appear to have a reliable tracking system to identify when required data for a conditional registration are still missing, identify and sort data that has been received, review the data and record the Agency staff conclusions, and incorporate the incoming data into the chemical assessment and product registrations in a timely and appropriate manner that reflects any hazards identified in the data. Therefore, products and technical products that are conditionally registered float through the registration system without any transparent or public access to assurances that the registrant has supplied the data that the registration was conditioned upon, or that those data have been reviewed and appropriately incorporated into the chemical registration. As such, EPA cannot reliably assure the public or itself that the conditions of the registration will be met because the agency's conditional registration program is so disorganized.

### **C. Other nano-scale antimicrobials are on the market without having undergone a full chemical risk assessment on the nano-scale material**

Nanosilver is not the only nano-scale antimicrobial that enjoys unregistered illegal widespread commercial use. There are other nano-metal pesticides that are commercialized, but not yet registered or safety tested. For example, Osmose, Inc., a wood preservation technologies company, advertizes nano-scale "micronized" copper-based biocides for wood treatment. A product report on their website confirms that an analysis of the treated wood "revealed the presence of nano-sized copper and iron particles (from grinding media) ranging from 10 to 700 nm in micronized treated wood..."<sup>41</sup> This product is already in widespread use; a 2009 media release from the manufacturer on the safety and performance of micronized copper technology boasts that "over 5 billion board feet of MicroPro treated wood has been sold since the product introduction in 2006."<sup>42</sup> The company claims that its micronized technologies are certified as an Environmentally Preferable Product (EPP), suggesting that its products are safe for the environment.<sup>43</sup> However, it appears that EPA has never been provided with any safety data for the nano-scale "micronized" formulation of this wood treatment biocide.

### **D. Problem with conditional registration generally**

EPA has overused conditional registrations, as they now represent the majority of active registrations. The EPA Office of Pesticide Programs (OPP) has over 16,000 pesticide product active registrations (that is, currently registered). Of these, over 11,000 (68%) are conditionally registered.

Although the proportion of active registrations that are conditional is disturbing, it is not a new occurrence. This is a long-standing pattern with EPA's pesticide office. Based on a search through the registration database<sup>44</sup>, of the 16,000 active products registrations:

- Almost 8,200 products have been conditionally registered ("CR status") since 2005,
- Approximately 5,400 products have had CR status since 2000,
- Over 3,200 products have had CR status since 1995, for 15 years.
- Over 2,100 products have had CR status since 1990, over 20 years.
- Over 800 technical products (that is, pure active ingredient), currently have CR status.

These astoundingly high numbers of product registrations that are still conditionally registered, even after so many years, raise several concerns.

First, it calls into question EPA's assertion that, "Ultimately, the Agency will use these data to determine whether the ingredient can be registered under FIFRA Section 3(c)(5)" when over 2000 active product registrations are conditionally registered for twenty years and almost 70% are conditionally registered at this time. (Decision Doc at 36).

Second, and more importantly, OPP may not be meeting its legal requirements under FIFRA to review each chemical every 15 years, address the hazards through mitigation measures, and incorporate the required mitigation through label amendments to address identified risks.<sup>45</sup> Instead, it appears that several thousand chemicals are "hiding out" in conditionally registered status, possibly avoiding registration review, while staying on the market despite significant data gaps. At a minimum, it shows an inexcusable lack of transparency and public accountability.

EPA must not register a pesticide until all the required data is provided, reviewed by EPA, and integrated into the chemical (ai) risk assessment and the product registration.

#### **IV. Conclusion**

PEA's proposed conditional registration of AGS-20 would violate FIFRA. EPA must cease allowing untested nanomaterials to flood consumer markets. EPA has misused its authority under FIFRA and has misinterpreted the use of conditional registrations. Further, EPA has failed to show that the use of AGS-20 will not cause unreasonable adverse effects and has failed to show that use of AGS-20 is in the public interest. In fact, the opposite is true – use of nanosilver-treated textiles is expected to lead to human exposures, environmental releases, and harm to non-target beneficial microbes. EPA must withdraw this proposal, and instead issue fines against companies that are marketing nanosilver pesticidal products without having undergone the full

registration process. If EPA were to do this, it is possible that the companies would work together to share the costs of generating the data required for a proper and complete registration application, leading to an even playing field for registrants, better data for EPA, and increased public confidence that pesticides are being regulated as the law requires.

Thank you for the opportunity to provide comments.

Respectfully,

Jennifer Sass, Ph.D., Senior Scientist, NRDC  
Mae Wu, JD, Staff Attorney, NRDC

These comments are supported by the following organizations:

*Alaska Community Action on Toxics* (Pamela Miller, Exec Dir)  
*Beyond Pesticides* (Jay Feldman)  
*Center for Environmental Health* (Caroline Cox)  
*Friends of the Earth US* (Ian Illuminato)  
*Organic Consumers Association* (Alexis Baden-Mayer, Esq.)  
*Pesticide Action Network North America* (Karl Tupper)  
*TEDX The Endocrine Disruptor Exchange* (Theo Colborn, Ph.D)

---

<sup>1</sup> SAP report, 2010. Memorandum from the FIFRA Scientific Advisory Panel meeting held November 3-5, 2009 on the Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products to EPA. January 26, 2010.

<http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>

<sup>2</sup> 7 U.S.C. §136a(a).

<sup>3</sup> Luoma SN. Silver nanotechnologies and the environment: old problems or new challenges. A report by Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts. 2008.  
[http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano\\_PEN\\_15\\_Final.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano_PEN_15_Final.pdf)

<sup>4</sup> Luoma SN. Silver nanotechnologies and the environment: old problems or new challenges. A report by Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts. 2008.  
[http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano\\_PEN\\_15\\_Final.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano_PEN_15_Final.pdf)

<sup>5</sup> Luoma SN. Silver nanotechnologies and the environment: old problems or new challenges. A report by Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts. 2008.  
[http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano\\_PEN\\_15\\_Final.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nano_PEN_15_Final.pdf)

<sup>6</sup> EPA RED Facts. Silver. June, 1993. <http://www.epa.gov/oppsrrd1/REDS/factsheets/4082fact.pdf>

<sup>7</sup> EPA RED Facts. Silver. June, 1993. <http://www.epa.gov/oppsrrd1/REDS/factsheets/4082fact.pdf>

<sup>8</sup> Papp T, Schiffmann D, Weiss D, Castranova V, Vallyathan V, Rahman O. Human health implications of nanomaterial exposure. *Nanotoxicology*, 2008. 2:1, 9 - 27

<sup>9</sup> SAP report at 10

<sup>10</sup> Braydich-Stolle L, Hussain S, Schlager JJ, Hofmann MC. In vitro cytotoxicity of nanoparticles in mammalian germline stem cells. *Toxicol Sci*. 2005 Dec;88(2):412-9. Epub 2005 Jul 13.

<sup>11</sup> SAP report at 10

<sup>12</sup> 7 U.S.C. § 136a(c)(7)(C).

<sup>13</sup> 7 U.S.C. § 136a(c)(7)(C).

<sup>14</sup> 40 CFR § 161.30(b)(2).

<sup>15</sup> 40 CFR § 161.101.

<sup>16</sup> 40 CFR §161.340.

<sup>17</sup> 40 CFR Part 161, Subpart D.

<sup>18</sup> 40 CFR § 161.101(b).

<sup>19</sup> 40 CFR 161.340(a), note (6).

<sup>20</sup> 40 CFR 161.340(a), note(18).

<sup>21</sup> Decision Doc at 3.

<sup>22</sup> 40 CFR § 161.35(c).

<sup>23</sup> 49 Fed. Reg. 42856 (Oct. 24, 1984).

<sup>24</sup> 7 U.S.C. § 136a(c)(7)(C).

<sup>25</sup> 40 CFR 161.340(a), note (6).

<sup>26</sup> 40 CFR 161.340(a), note(18).

<sup>27</sup> Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.  
[http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F)

<sup>28</sup> Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.  
[http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F)

<sup>29</sup> Gordon, T., Lung Chi, C., Cohen, Beverly S. Final Report: Role of particle agglomeration in nanoparticle toxicity. EPA Grant No. R832528. 2008.  
[http://cfpub.epa.gov/ncer\\_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F](http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/7814/report/F)

<sup>30</sup> UConn News. Scientists study health implications of products using nanosilver. February 18, 2009.  
<http://news.uconn.edu/2009/February/rel09019.html>

ScienceNews. Nanosilver disinfects – but at what price? Janet Raloff. November 30, 2008.  
[http://www.sciencenews.org/view/generic/id/38913/title/Nanosilver\\_disinfects\\_%E2%80%94\\_but\\_at\\_what\\_price%3F](http://www.sciencenews.org/view/generic/id/38913/title/Nanosilver_disinfects_%E2%80%94_but_at_what_price%3F)

---

Perkins, C., M. Levin and S. DeGuise. 2008. The Immunomodulatory Effects of Nanosilver Upon in vitro Exposure. Society of Environmental Toxicology & Chemistry North American annual meeting: Tampa (Nov. 20).

Shin, S.-H., et al. 2007. The Effects of Nano-Silver on the Proliferation and Cytokine Expression by Peripheral Blood Mononuclear Cells. *International Immunopharmacology* 7(Dec. 15):1813

<sup>31</sup> 7 U.S.C. 136a(c)(7)(C).

<sup>32</sup> Memorandum from the FIFRA Scientific Advisory Panel meeting held November 3-5, 2009 on the Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products to EPA. January 26, 2010, p 10.

<http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>

<sup>33</sup> Ibid.

<sup>34</sup> Ibid.

<sup>35</sup> Ibid at 11.

<sup>36</sup> Cincinnati Children's Hospital. History of lead advertising: Do not forget the children. See as an example, the children's paint book issued by the lead paint industry titled, "The Dutch boy conquers old man gloom" (1929). <http://www.cincinnatichildrens.org/research/project/enviro/hazard/lead/lead-advertising/children.htm>

<sup>37</sup> Washington Post. EPA to regulate nanoproducts sold as germ-killing. Rick Weiss, Nov 23, 2006.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/22/AR2006112201979.html>

PPDC discusses nanotechnology and pesticides. Blog by Lynn L. Bergeson. May 5, 2010

<http://nanotech.lawbc.com/2010/05/articles/united-states/federal/ppdc-discusses-nanotechnology-and-pesticides/>

<sup>38</sup> Jordan, W. Nanotechnology and Pesticides. Pesticide Program Dialogue Committee, April 29, 2010. <http://www.epa.gov/pesticides/ppdc/2010/april2010/session1-nanotec.pdf>

<sup>39</sup> Memorandum from the FIFRA Scientific Advisory Panel meeting held November 3-5, 2009 on the Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products to EPA. January 26, 2010.

<http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>, pg 6-9.

<sup>40</sup> Senjen R and Illuminato IS. Nano and Biocidal Silver: Extreme Germ Killers Present a Growing Threat to Public Health. Rep. Washington, DC: Report by Friends of the Earth, 2009.

<sup>41</sup> A comprehensive review of copper-based wood preservatives with a focus on micronized or dispersed copper systems. MH Freeman and CR McIntyre. 2008. *Forest Prod. J.* 58(11): 6-27. <http://www.osmosewood.com/micropro/images/Nov08-FPJ-Feature.pdf>

<sup>42</sup> Osmose and MicroPro media release. Consumer safety and product performance of micronized copper technology confirmed. February 10, 2009. [www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf](http://www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf)

<sup>43</sup> Osmose and MicroPro media release. Consumer safety and product performance of micronized copper technology confirmed. February 10, 2009. [www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf](http://www.osmosewood.com/pressroom/images/Osmose%20Press%20Release%20Feb%2010%202009.pdf)

<sup>44</sup> National Pesticide Information Retrieval System, NPIRS Public. <http://ppis.ceris.purdue.edu/>

<sup>45</sup> 7 U.S.C. § 136a(g)