UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 19, 2015

The International Center for Technology Assessment
660 Pennsylvania Avenue, S.E., Suite 302
Washington, DC 20003

Subject: EPA Response to "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides"

Dear Petitioners:

Enclosed, please find the Agency's response to your petition, "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides," submitted on May 1, 2008. On November 19, 2008, EPA announced in the Federal Register its receipt of the ICTA petition and solicited public comments. The petition, supporting documents, and comments may be found in the public docket for this action at www.regulations.gov in Docket ID # EPA-HQ-OPP-2008-0650.

In summary, and as related more specifically in our response, the petition requested that EPA regulate products containing nanoscale silver as pesticides, and to assess them as new and different from macro-silver products.

On December 16, 2014, you filed a lawsuit against EPA alleging that EPA had failed to respond to the petition. The parties agreed to an additional 30 days for EPA to file an answer. The enclosure addresses the issues you raise in your petition.

Sincerely,

Jack E. Housenger, Director
Office of Pesticide Programs

Enclosure: EPA Response to "Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides"

EPA Response to Petition from International Center for Technology Assessment Relating to Regulation of Nanoscale Silver as a Pesticide

On May 1, 2008, the International Center for Technology Assessment (ICTA) and thirteen other organizations ("Petitioner") filed a Petition for Rulemaking requesting that EPA regulate products containing nanoscale silver as pesticides, and to assess them as new and different from macro-silver products. The Petitioner states that there has been a rapid increase in the number of products containing or advertised as containing manufactured or engineered nanoscale materials, and provides a list of such products in Appendix A of the Petition. The Petition also references scientific data believed to provide evidence that nanoscale materials can have fundamentally different properties from the non-nanoscale or bulk forms of the same compounds. Thus, Petitioner states that such products may pose new environmental and human health risks. The Petitioner asserts that statutory and regulatory exemptions are not available for such products, and requests that the Agency provide adequate regulatory oversight for this emerging technology, identifying a number of specific requested regulatory actions.

On November 19, 2008, EPA announced in the Federal Register its receipt of the ICTA petition and solicited public comments [73 FR 69644]. The comment period closed on March 20, 2009. EPA received more than 1500 public comments in response to the Federal Register notice announcing its receipt of ICTA's petition and soliciting comments. Many comments were identical copies of a form letter submitted as the result of a letter-writing campaign. The majority restated the requests in the petition, and reiterated some of ICTA's concerns about the potential dangers that nanoscale silver may pose to the environment and public health. Many of the comments also noted that the properties which make nanotechnology useful in new products may also render nanoparticles harmful to the environment. These comments, as well the petition and supporting documents, may be found in a public docket for this action at www.regulations.gov in Docket ID # EPA-HQ-OPP-2008-0650.

Some comments were opposed to the requests contained in the ICTA petition. For instance, general comments were made that silver occurs naturally, and that there is no real evidence of risk with respect to nanoscale silver, only conjecture. Other comments stated that the petition amounted to another case of government interference and that individuals should be allowed to choose what goes into their own bodies. Comments also were provided opposing the petition on the grounds that the problems cited were "artificial" and that silver in nano-form will return to its normal state once it goes back into the environment. There were additional concerns that if ICTA possessed concrete information on the harmful effects of nanoscale silver, this information should be shared and its validity should be determined. Other concerns characterized the petition as a wasteful effort to direct the EPA to regulate something that it already has the authority to regulate.

Some commenters included literature citations and articles either supporting or refuting the Petitioner's requests. The Agency does not regard it as necessary to present a review of this body of research to respond to the requests contained in the petition as EPA scientists have been reviewing the relevant literature and will continue to review any relevant literature in the course of any Agency action on pesticides containing nanoscale silver. Examples of such reviews can be found in the dockets for recent final and proposed registration decisions relating to pesticides containing nanoscale silver. See, HeiQ AGS-20 Final Decision (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2009-1012) and Proposed Decision for Nanosilva NSPW-L30SS (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2012-0594).

Approximately 15 detailed comments were received from industry, academia, public interest groups, and other interested parties addressing specific regulatory issues raised in the ICTA petition. Some of

these comments agreed with the views advanced in the petition, and others opposed those views.

Based on consideration of the petition and the significant public comments, EPA is granting some of the Petitioner's requested actions and denying others. As a general matter, EPA is granting Petitioner's request to use its authorities in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetics Act (FFDCA), and related regulations to address concerns relating to the potential for differing toxicity profiles as between macroscale and nanoscale silver ingredients that may be regulated under FIFRA and the FFDCA and that are found to have a pesticidal purpose. EPA will use its discretion on how best to address these concerns under each of these authorities. This applies to applications for pesticides containing a new nanosilver ingredient or with respect to registration review of existing registrations. EPA will also use its enforcement discretion on how best to address the potential for the distribution and sale in the United States of unregistered pesticides, including with respect to products of the type listed in Appendix A of the Petition, but will not commit to any particular enforcement action. EPA, however, is denying Petitioner's requests to classify all nanosilver as a pesticide, to amend existing data regulations and to establish a tolerance for nanosilver unrelated to a specific application for a registration necessitating such tolerance. EPA is also denying Petitioner's request to release confidential production, distribution, sale or inventories of nanosilver products because such release is unnecessary given the transparency and public participation opportunities currently available.

EPA's decisions with respect to each of Petitioner's requested actions, along with the significant public comments EPA received addressing those requested actions, are discussed in more detail below. [1]

I. ICTA Requested Action: Classify nanosilver as a pesticide and require the registration of nanosilver products as pesticides

Petitioner:

Petitioner requests that EPA classify all products containing nanoscale silver as pesticides and require manufacturers to register nanoscale silver products as pesticides pursuant to FIFRA. Furthermore, in reference to nanoscale silver, Petitioner requests that EPA clarify that pesticidal intent and public health claims can be both implicit and explicit, and that manufacturers cannot avoid pesticide classification (and registration under FIFRA) simply by stripping their products of label language recommending the product for use against a pest. Petitioner states that in the absence of an express pesticidal claim by the manufacturer or distributor, "[i]ndustry claims and general public knowledge can make a product pesticidal." Thus, Petitioner concludes that the general advertising of the germ-killing properties of nanosilver creates public knowledge and an expectation that every nanosilver containing product is an antimicrobial pesticide.

In support of its position that every nanosilver containing product is a pesticide under FIFRA, Petitioner asserts that certain statutory and regulatory exclusions and exemptions do not apply to nanosilver products such as those identified in Petitioner's Appendix A list. First, Petitioner asserts that the regulatory treated article exemption (40 CFR §152.25(a)) should not apply to any nanosilver products. Petitioner states that many nanosilver products make express claims of protection against pests such as bacteria and viruses, and as a result do not qualify for the treated article exemption. Petitioner also argues that because nanosilver is not currently registered as a pesticide active ingredient or labeled for use in the treated articles in question, the treated article exemption cannot properly apply.

[1] For the purpose of this petition response, EPA has not accepted or rejected any definition of "nanoscale silver" or "nanosilver" offered by Petitioner or commenters, but is responding to the broad requests made by ICTA on nanoscale silver products.

Second, with regard to FIFRA registration exclusions for substances regulated under other statutes, Petitioner argues that only nanoscale products that are "approved by FDA pursuant to its drug approval process" should be exempt from registration under FIFRA, not products like dietary supplements that are not subject to the FDA pre-market drug approval process.

Third, Petitioner asserts that the exemption from FIFRA registration for products intended for use only against "microorganisms, internal parasites, or nematodes in or on living humans or animals and labeled accordingly" does not apply to any of the consumer products listed in Appendix A of the petition.

Public Comments:

EPA received comments on these issues from the American Chemistry Council, the Copper Development Association, Crop Life America, the Environmental Defense Fund, the National Association of Clean Water Agencies (NACWA), Natural-Immunogenics Corporation, Purest Colloids, Inc., and several individuals. Generally, these commenters urged EPA to require registration of products containing nanoscale silver that make pesticidal claims, but did not take the Petitioner's position that every nanosilver product has a pesticidal intent and therefore should be required to be registered as a pesticide under FIFRA.

The American Chemistry Council and Crop Life America stated that EPA currently has the statutory authority and appropriate regulations, policies, and procedures in place in order to regulate nanoscale silver products that have pesticidal uses, and disputed Petitioner's assertion that rulemaking or other regulatory changes are necessary.

The Copper Development Association further noted that many nanoscale silver products are intended for control of public health pests, and therefore that the Agency should require efficacy data to support the public health claims. Crop Life America commented that "FIFRA as currently implemented is well-suited to address the issues raised by nanomaterials that may have pesticidal uses" giving as an example FIFRA Section 6(a)(2) requirements on registrants to provide adverse effects information.

The Environmental Defense Fund (EDF) joined ICTA in noting that pesticidal claims can be both implicit and explicit and that manufacturers cannot avoid pesticide classification simply by stripping their products of pesticidal labeling claims. EDF further stated that limiting regulation of nanoscale silver to "claims-based uses simply does not make sense." EDF states that because of the ample evidence provided by ICTA that manufacturers are using nanosilver for its pesticidal properties, the burden should be shifted to the manufacturer to demonstrate that a product is not intended for use due to its pesticidal properties.

The Copper Development Association commented that many nanoscale silver products are currently being marketed under the treated articles exemption when in fact they require registration. The American Chemistry Council challenged Petitioner's assertion that nanosilver-treated products should never qualify for the treated article exemption, and urged EPA to employ a case-by-case analysis to determine the applicability of the treated article exemption.

Natural Immunogenics Corporation, Purest Colloids, Inc. and several individuals commented that EPA should not regulate dietary supplements containing nanoscale silver. These commenters argue that FDA, not EPA, has statutory authority for regulating dietary supplements, and assert that the dietary supplements do not meet the definition of a pesticide.

EPA Response:

EPA is partially granting and partially denying Petitioner's requested action. Specifically, EPA is

granting Petitioner's request to treat as pesticides under FIFRA products containing nanoscale silver if intended for pesticidal purposes, as defined in FIFRA and EPA regulations, and subject to other regulatory exemptions and controls. EPA agrees that all relevant information will be considered in making this determination, even in the absence of explicit pesticidal claims. EPA is denying Petitioner's request, however, for EPA to conclude that all products containing nanosilver are intended for a pesticidal purpose or to generally require manufacturers of any product containing nanosilver to pursue registration under FIFRA. Further, EPA disagrees with Petitioner's assertion that the treated article exemption does not apply to products containing nanosilver. Finally, although EPA is denying Petitioner's request to treat all products containing nanosilver as pesticides, to the extent that any unregistered pesticides are being sold or distributed in the United States, EPA will address them, as appropriate, through its general FIFRA enforcement program.

Is nanosilver a "pesticide"? EPA does not have the foundation to classify all nanosilver ingredients or products containing nanosilver as pesticides.

EPA's authority for requiring registration extends only to a substance that is a "pesticide," as that term is defined in FIFRA and applied in EPA regulations. "Pesticide" is defined, in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." FIFRA 2(u) (emphasis added). The FIFRA definition of "pesticide" also expressly excludes a number of substances, such as certain liquid chemical sterilants. Thus, those substances cannot be classified as a pesticide. In addition, as Petitioner recognizes, the definition of "pest" in FIFRA section 2(t) explicitly excludes "viruses, bacteria, and other microorganisms on or in living man." Similarly, if the "pest" targeted by the nanosilver is a "fungus" as defined under FIFRA section 2(k), the nanosilver is not a pesticide if the targeted fungus is "on or in living man or other animals" or "on or in processed food, beverages, or pharmaceuticals." Under EPA regulations, 40 CFR 152.5(d), EPA has also extended this statutory exclusion to any fungus "on or in ... cosmetics (as defined in FFDCA section 201(i))." In addition, as Petitioner also notes, EPA has by regulation identified a set of substances (e.g., deodorizers and cleaning agents), that are not considered to be pesticides unless a pesticidal claim is made on the label or in connection with the substance's sale or distribution. 40 CFR 152.10. As a result, products that are intended solely for uses that fall within the statutory or regulatory exclusions are not pesticides and are not subject to the requirements for registration. Please see 40 CFR 152.6 for a discussion of these and other statutory exclusions, and 40 CFR 152.5 for EPA's regulations on what is a "pest" and 40 CFR 152.8 for a list of products that are deemed not for use against a "pest."

Further, EPA's authority to regulate a product as a pesticide extends only to substances or mixtures intended for a pesticidal purpose. As Petitioner and commenters note, EPA's implementing regulations at 40 CFR 152.15 state:

> A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:
>
> (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
>
> (i) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
>
> (ii) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
>
> (b) The substance consists of or contains one or more active ingredients and has no

> significant commercially valuable use as distributed or sold other than (1) use for pesticide purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
>
> (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

EPA agrees with Petitioner that, based on the plain language of the regulation, the mere absence of an express claim on the product or labeling does not fully address whether a product is intended for a pesticidal purpose. Thus, removing an explicit pesticidal claim from a product's labeling or advertising does not necessarily mean that the product no longer qualifies as having a pesticidal purpose. As EPA explained when first adopting these regulations, "[t]he second and third criteria both are intended to address longstanding enforcement problems in which neither labeling nor advertising clearly states or implies that the product is a pesticide, but the product is sold under circumstances in which it is clear that the product is intended for a pesticidal purpose." 53 FR 15952, at 15954 (May 4, 1988). Thus, EPA also agrees with Petitioner's position that "[i]ndustry claims and general public knowledge" under these provisions can be taken into consideration, along with other relevant information, in determining whether a substance is used for a pesticidal purpose.

However, EPA disagrees with Petitioner's position that nanosilver is specifically and solely used for its antimicrobial properties and that research shows no other significant commercially valuable use for nanosilver. Petitioner cites to no support for its position and there is evidence contrary to this claim. While EPA agrees with Petitioner that silver and nanosilver ingredients have inherent bactericidal properties, other well-known but non-pesticidal attributes of silver and nanosilver may instead be the intended use of such ingredients. For example, public literature indicates that silver has many other properties that allow uses for other purposes, such as in analytical instrumentation, cloud seeding, electroplating, mirrors, photography, and catalysts (Etris, S.F. and Cappel, C.R., Silver Compounds. Kirk-Othmer Encyclopedia of Chemical Technology. 16 May 2003); *see also*, Comments of Nanotechnology Industries Association, at page 5. Consistent with this information, it is EPA's judgment that there are products listed in Petitioner's Appendix A that appear to have non-pesticidal nanosilver uses (e.g., nanosilver based conductive inks for the generation of electronic devices which take advantage of the electrical conductive properties of nanosilver). As EPA cautioned when adopting 40 CFR 152.15, "a certain degree of judgment must be exercised in deciding whether a substance meets this definition. On the other hand, the Agency believes that a large percentage, if not the majority, of pesticide active ingredients are clearly identifiable either as pesticides or as multi-purpose substances, and that the Agency will rarely be compelled to use this criterion alone to judge whether a substance is a pesticide." 53 FR 15952, at 15954 (May 4, 1988). For the reason noted above, this position holds true in this case as well, and thus EPA cannot conclude that nanosilver generally or always is used for a pesticidal purpose.

In sum, for the reasons noted above, EPA denies Petitioner's request that EPA categorically classify nanosilver as a pesticide under FIFRA. EPA likewise disagrees with commenter EDF's suggestion that it would be appropriate to shift the burden to all manufacturers using any nanosilver ingredients in products, to come forward and demonstrate that the products have no pesticidal intent. However, EPA agrees that, pursuant to 40 CFR 152.15, EPA may consider labeling, advertising, industry claims or general public knowledge in determining whether a particular product containing nanosilver is intended for a pesticidal purpose. The determination in such cases would be fact specific, typically based upon information on the use patterns intended, the claims or other advertising used to distribute or sell the

ingredient or product, and any other information or knowledge made known to or known by the distributor or seller.

Do the statutory or regulatory exclusions apply to Appendix A listed products?: EPA disagrees with Petitioner's assertion that none of the products listed in Appendix A may be subject to a statutory or regulatory exclusion. Petitioner specifically states that none of the listed products are the types of human or animal drugs excluded from FIFRA regulation and asserts therefore that EPA should subject those products to registration under FIFRA. The basis for Petitioner's position is unclear. The statute and regulations are clear that ingredients that may be in dietary supplements, bandages, catheters, colloidal creams, or certain personal care items, if intended to address excluded pests such as viruses, bacteria or other microorganisms on or in living man, or fungi on or in living man, processed food, beverages or cosmetics, are not subject to FIFRA jurisdiction. Because several of the Appendix A listed products appear to be intended for such excluded pests, EPA cannot agree with Petitioner's position that the exclusion does not apply to such products; these exclusions are not limited to human or animal drugs.

However, EPA generally agrees with Petitioner that products may have a pesticidal purpose even though labeled for use against an excluded pest or even if presumed by regulation not to have a pesticidal purpose. For example, a product advertised for use against nonexcluded and excluded pests may be subject to FIFRA registration; the nonexcluded pest use would be considered in determining whether the product is subject to FIFRA regulatory authority. Likewise, if a product is labeled for use against an excluded pest, but is in fact generally used to address a non-excluded pest, the product may then be found to have pesticidal purpose and subject to FIFRA regulatory authority, i.e., if there is actual or constructive knowledge that the product is intended for a pesticidal purpose pursuant to 40 CFR 152.15(c). In addition, products ordinarily presumed by regulation not to be intended for a pesticidal purpose lose the benefit of the presumption if pesticidal claims are made in connection with the product labeling or advertising. For example, a deodorizer or cleaning product labeled or advertised to control bacteria, would lose the benefit of the regulatory presumption that the product is not intended to have a pesticidal purpose; the plain language of the regulatory presumption only allows the presumption if a pesticidal claim is not made on their labeling or in connection with sale and distribution. 40 CFR 152.10. Appendix A lists certain products that might have been assumed to be a deodorizer or cleaning product subject to the regulatory presumption that the product has no intended pesticidal purpose. However, the language quoted in Appendix A as taken from product advertising appears to make pesticidal claims (e.g., sanitizer or sterilization). Such language would disqualify the product from the regulatory presumption, and registration under FIFRA may then be required if the product is intended to be offered for sale or distribution in the United States.

EPA routinely applies the statutory and regulatory criteria to determine on a case-by-case basis whether products, such as the types of silver- and nanosilver-based products listed in Petitioner's Appendix A, have a pesticidal purpose. For example, EPA has registered under FIFRA ingredients used in some of the types of products listed on Appendix A, such as air and water filters, food storage containers, heating and ventilation systems, textiles, handrails, door knobs, children's toys, washing machines, refrigerators, humidifiers, hair brushes, paints, antibacterial sprays, sanitizers, wet wipes, cell phones, bidets, detergents and cleaners, computer mice and keyboards, pet sprays and pet shampoos. Further, as Petitioner notes, there are specific Appendix A listed products that EPA has determined to be pesticides and which EPA found in violation of FIFRA requirements. See, EPA Region 9 Press Release, March 5, 2008 (IOGEAR); and EPA Press Release, December 15, 2010 (Kinetic Solutions). Thus, any such products listed on Appendix A and advertised as containing nanosilver for antimicrobial purposes may

be products with a pesticidal purpose and subject to FIFRA registration requirements, unless, as discussed further below, otherwise subject to a regulatory exemption.

However, certain other products listed in Appendix A, even assuming antibacterial claims, may not be subject to FIFRA jurisdiction or could not be further considered. This is because the products (i) are no longer advertised as being available (e.g., ARC Technologies); (ii) no longer have active websites (e.g., nanbabies.com); or (iii) or appear to be available only in foreign markets (it is a violation under FIFRA section 12(a)(1)(A) only if the company is selling or distributing unregistered pesticides in the United States).

In sum, EPA agrees with Petitioner that many of the claims made for products listed in Appendix A appear to communicate a pesticidal purpose and such a claim could bring a product within FIFRA jurisdiction, assuming no statutory or regulatory exclusions apply and assuming the product is currently offered for sale or distribution in the United States. EPA strongly encourages manufacturers of the products listed in Appendix A (and manufacturers of any products similar to those identified by Petitioner but not listed) to consult with the Agency on whether registration of their products is required, particularly if the products are of the types described above as typically having ingredients that are registered under FIFRA. To the extent that any unregistered pesticides are being offered for sale, sold or distributed in the United States, EPA will address them, as appropriate, through its general FIFRA enforcement program.

Which regulatory exemptions might apply to Appendix A listed products?: Petitioner and commenters reference a number of potential regulatory exemptions but assert that the exemptions do not or should not apply to Appendix A listed products or products containing nanosilver. Those issues and exemptions are addressed below.

Products Adequately Regulated by Another Federal Agency

Pursuant to FIFRA section 25(b)(1), EPA may exempt from registration products EPA determines to be adequately regulated by another federal agency. This exemption authority is only applicable if the product is otherwise not statutorily excluded from FIFRA coverage. The determination to exempt a product under this authority has been made for biological control agents and certain non-liquid sterilants, for example. 40 CFR 152.20. Thus, any nanosilver ingredient in those kinds of pesticidal products are exempt from FIFRA registration.

EPA agrees that none of the Appendix A products appear to be covered by either of these regulatory exemptions. EPA also generally agrees with the Petitioner that it should not be assumed that simply because another federal agency regulates a product that FIFRA jurisdiction and requirements do not also apply; there are products that can be subject concurrently to EPA's and another federal agency's authority and review.

Products Otherwise Exempt Under FIFRA Section 25(b)(2) - The Treated Article Exemption.

Pursuant to FIFRA section 25(b)(1), EPA may exempt from registration products EPA determines to be of a character not requiring regulation under FIFRA. EPA has issued exemptions for a number of types of pesticides under this authority. 40 CFR 152.25. However, the only FIFRA section 25(b)(2) regulatory exemption addressed in the petition and in comments relates to use of registered pesticides to treat articles. 40 CFR 152.25(a). That regulation exempts "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use." Thus, an article treated with a pesticide

may be exempt from FIFRA registration if the pesticide is added only to protect the article itself and the pesticide added to the treated article "is registered for such use."

EPA disagrees with Petitioner that the treated article exemption may not and should not apply to any nanosilver pesticide products. Petitioner asserts that because nanosilver specifically was not registered as a pesticide active ingredient or labeled for use in treated articles, the treated article exemption cannot properly apply. However, application of the treated article exemption is available if a registered pesticide is used, consistent with any terms and conditions for use of the registered pesticide. Thus, pesticide products registered as containing silver but later found to contain nanosilver are nonetheless registered and as long as a registered silver product is used to treat an article consistent with the terms and conditions on such use, the treated article exemption may apply.

EPA agrees with Petitioner that articles that are pesticides with express claims of protection against pests such as bacteria and viruses may not qualify for the treated article exemption. EPA agrees that this is explained in P.R. Notice 2000-1; PR Notice 2000-10; http://www.epa.gov/pesticides/factsheets/treatart.htm. EPA also agrees with Petitioner that a number of products listed in Appendix A appear to include antimicrobial claims to protect more than the article itself, claims which are otherwise impermissible under the treated article exemption. To the extent that any unregistered pesticide articles are being sold or distributed in the United States, EPA will address them, as appropriate, through its general FIFRA enforcement program. EPA also agrees with Petitioner and commenter Copper Development Association that products intended to control pests of significant public health importance must be supported in registration with product performance data. See, 40 CFR parts 158 and 161. A list of such pests was published in 2002 in Pesticide Registration Notice 2002-1, which is available online at http://www.epa.gov/PR_Notices/pr2002-1.

In sum, EPA agrees that none of the Appendix A listed products appear to be covered by the regulatory exemption for products found to be adequately regulated by another federal agency. However, EPA disagrees with Petitioner's position that the regulatory exemption for treated articles can never apply to articles containing nanosilver, but agrees that if claims relating to certain pests such as viruses are made, the product should merit further investigation to determine whether the product is within FIFRA jurisdiction and thus subject to registration requirements.

II. ICTA Requested Action: Determine that nanosilver is a new pesticide that requires a new pesticide registration

Petitioner:

Petitioner states that nanoscale materials have unique characteristics affecting the toxicological potential of the material, including: size, surface area, surface charge, solubility, shape or physical dimensions, surface coatings, chemical composition and aggregation potential. For example, Petitioner states that "[b]ecause nanoparticles of silver have a greater surface area than larger particles of silver, nano-silver is more chemically reactive and more readily ionized than silver in larger particle form. Nano-silver therefore has greater antibacterial and toxic effects compared to larger silver particles partly because it is more readily converted to silver ions. There is also preliminary evidence that nano-silver can exert effective antibacterial action at a considerably lower concentration than that of silver ions, suggesting that the antibacterial properties and toxicity of nano-silver only by its chemical composition and by the production of silver ions alone." Petitioner concludes that these and other unique characteristics result in different product compositions, pest claims, and product use patterns, and therefore different risks and benefits, than macro-scale products. Because of these differences, Petitioner states that Part 158 data submitted for macro-versions are not applicable to the nano-version of the material ("the biological

activity of nanoparticles is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies") and that "a different risk assessment based on actual characteristics of the nano-pesticide" is necessary to make the statutory findings for registration of the nano-pesticide product. Petitioner further concludes that as a result of these differences and issues, "nano-pesticides are not covered by existing registrations of conventional pesticides" and thus, for example, a nanosilver ingredient cannot be substituted for a bulk silver ingredient. For all of these reasons, Petitioner requests that EPA classify nanoscaled pesticides, with specific focus on nanosilver, as new pesticides and asserts that EPA may register such pesticide products under its FIFRA section 3(c)(7) authority given the need for additional data to assess the nanosilver ingredient.

Finally, specifically with respect to nanosilver, for the reasons noted above, Petitioner takes the position that "nano-silver is a new active ingredient of a new pesticide that requires its own separate pesticide registration process that accounts for the nano-specific risks assessments, toxicology, and exposures" noted above. In the alternative, and citing to EPA regulations at 40 CFR 152.3, Petitioner takes the position that nano-silver is a 'new use' of a previously registered silver pesticide because nano-silver requires establishment of a tolerance and no tolerance has been set; currently unregistered nano-silver products have an aquatic, terrestrial, outdoor or forestry use pattern and nanosilver is not currently registered for those use patterns; and nano-silver new use patterns result in a significant increases in exposures and new routes of exposures.

Public Comments:

EPA received specific comments on this issue from the Environmental Defense Fund. Consistent with Petitioner's request, EDF urged EPA to classify nanosilver as a separate substance from bulk silver based on nanomaterial's capacity for unique and different properties. They note that hazards associated with nanoscale materials cannot be readily inferred or extrapolated from data pertaining to the bulk-scale materials, and that it is therefore important to collect nano-specific hazard and exposure data for the risk evaluation. In contrast, Purest Colloids, Inc. takes the position that ICTA's request is "premature in the absence of scientific agreement" on the risks from nanoscale products and is thus arbitrary and capricious "[a]bsent further scientific discovery." Thus, Purest Colloids, Inc. concludes that absent a more reasoned analysis, Petitioner's request, if accepted, would be in violation of the Administrative Procedure Act (APA). The Natural-Immunogenics Corp. takes the position that "to the extent one could find a basis for EPA to act, regulations already in place provide all authority necessary to act" and that under APA precedent, EPA must supply a reasoned analysis for assessing nanosilver separately from other silver compounds based on size. Purest Colloids, Inc. and Natural-Immunogenics Corp. also take the position that EPA action absent a scientific basis would be in violation of the Data Quality Act (DQA).

EPA also received numerous comments from Crop Life America, American Chemistry Council and others indicating that existing FIFRA authorities are sufficiently broad to address any concerns and that sweeping regulatory changes are not necessary.

EPA Response:

EPA is granting Petitioner's request to review the health and environmental impacts from use of a nanosilver ingredient in a pesticide product based on nanosilver data for the portion released as nanosilver and based on macro-scaled silver for the portion released as silver ions, and agrees that, in the near-term, FIFRA section 3(c)(7)(C) is appropriate authority for review of applications for registration of pesticide products containing new nanosilver ingredients.

EPA agrees with Petitioner and commenters that, because of the unique characteristics of nanosilver, products containing nanosilver may have different toxicity and / or fate profiles than products containing only macro-scaled silver or other silver ingredients. This proposition was the subject of the 2009 SAP review and report (materials available at http://www.epa.gov/scipoly/sap/meetings/2009/110309ameeting.html), and has since been a feature of recent assessments for pesticide products containing nanosilver. See, HeiQ AGS-20 Final Decision (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2009-1012) and Proposed Decision for Nanosilva NSPW-L30SS (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2012-0594). As explained in the background for each, until recently, EPA generally has not focused on physiochemical properties of a silver-based ingredient in its assessment of the toxicity of the ingredient. However, the SAP indicated and EPA agrees that a nanosilver ingredient may have a toxicity profile that is different from macro-silver ingredients. The Agency is aware of no new data to suggest that the SAP concerns are misplaced or that the hazard for the nanosilver in or released from use of a pesticide product can be fully characterized using silver ion hazard data only. The SAP also cautioned about extrapolating from one nanosilver formulation to another when assessing hazards because differences in particle formulation (e.g., coating and inert ingredients) may affect biological activity, among other things. Further evaluation of this concern is still ongoing. Thus, EPA continues to agree with the SAP concerns raised in 2009 and EPA generally agrees with Petitioner's concerns that nanosilver ingredients have the potential to have a human health and environmental toxicity profile that is different from that of a macro-scaled silver counterpart or from other nanosilver ingredients with different physiochemical properties.

Taking the above information into account, EPA consequently agrees that the health and environmental toxicity profile for a macro-silver material would generally not be sufficient alone to make statutory findings necessary for registration of products containing nanosilver. Instead, EPA believes it is appropriate to consider the human and environmental toxicity data for both the silver ion and for the nanosilver material in or released from use of the proposed product, and as a result to consider particular proposed use patterns and routes of likely exposures, including exposures to infants and children, to the silver and to the nanosilver in or released from the proposed product. As a result, EPA agrees that existing data requirements may need to be adapted for nanosilver ingredients in a proposed pesticide product and other new data may need to be required. However, this has been done on a case-by-case basis, focusing on the composition of the proposed pesticide product and the properties of the nanosilver material and taking into consideration any additional data submitted or otherwise available for the silver and nanosilver material in the product. Because EPA's decision is grounded in the current understanding of the science and data available with respect to nanosilver, EPA disagrees with the premise of Purest Colloids comments that further research is necessary before EPA may or should assess nanosilver separately from macro-scaled silver. The information before EPA at this time provides the reasoned basis, as requested by Natural-Immunogenics, for assessing nanosilver separately from macro-silver under FIFRA authorities. Therefore, EPA disagrees with the position that the APA or DQA may preclude EPA from assessing the risks of nanosilver separately from macro-silver under FIFRA authorities.

EPA likewise agrees with Petitioner that because of the novel physiochemical characteristics of nanosilver, applications for a pesticide product containing a new nanosilver material may need to be assessed as EPA would assess a new active ingredient. If upon evaluation of such an application EPA determines additional data are required, EPA agrees with Petitioner and numerous commenters that FIFRA section 3(c)(7)(C) provides authority for granting a registration conditioned upon submission of the additional data, assuming the requisite findings can be made. In addition, EPA has initiated the

registration review process for silver and nanosilver registrations, which includes consideration of existing registrations that may contain nanosilver, and these issues and any data requirements will be considered in the course of those reviews. Thus, EPA agrees with Natural-Immunogenics and other commenters that FIFRA and related regulations already in place provide sufficient authority for EPA to act to address any risk concerns with respect to pesticides containing nanosilver.

In sum, in EPA's judgment, and taking into consideration the issue and concerns noted above by the SAP and that additional data on nanosilver may be needed, EPA agrees that it may be appropriate to consider applications for most pesticide products containing a new nanosilver ingredient under its FIFRA section 3(c)(7)(C) authority. As has been done recently, EPA's review of such applications will involve a review of data on nanosilver and macro-silver, and will take into consideration the potential for differences in the toxicity profiles for each.

III. ICTA Requested Action: Analyze the potential human health and environmental risks of nanosilver pursuant to EPA's statutory obligations under FIFRA, FQPA, ESA and NEPA

Petitioner:

Petitioner requests that the Agency determine that the registration of nanosilver poses unreasonable risk to man or the environment and require additional data to address "unknowns" with regard to human health and the environment. According to the Petitioner, the use of nanosilver as an antimicrobial agent is widespread and the products containing nanosilver result in direct human contact and / or are directly released into the environment, thus increasing the potential for bioaccumulation. The Petitioner cites the adverse environmental impacts to invertebrate species and the capacity for organisms that are higher on the food chain to be affected by direct uptake and trophic transfer. Further, the Petitioner states that the enhanced toxic properties and toxicity mechanisms may result from the potential for nanomaterials to be more reactive than larger particles of the same material.

Petitioner also requests that the Agency assess the potential impacts of nanosilver on infants and children that will result from aggregate exposures and, prior to setting a tolerance, take into consideration the Food Quality Protection Act's (FQPA's) standards for child safety. Petitioner is concerned that the use of many of the products listed in Appendix A may result in pesticide residues in or on food and thus that EPA must conclude that "there is a reasonable certainty that no harm will result from aggregate exposures to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information" before granting a tolerance or tolerance exemption. The Petitioner cites studies that have addressed the potential for nanomaterials to present serious toxicity risks for human health.

Further, the Petitioner notes that any EPA activities or oversight must comply with the Endangered Species Act (ESA), especially Section 7, which requires consultation with the US Fish and Wildlife Service and /or the National Marine Fisheries Service at the earliest possible time to determine whether any action may affect listed endangered species. Petitioner lists numerous protected species that might be negatively impacted by releases of nanosilver and concludes that assessments and findings for macro-scaled silver are not sufficient to protect species from release of nanosilver.

Finally under this requested action, the petitioner has stated that the Agency must comply with the National Environmental Policy Act (NEPA) to assess the environmental impacts of EPA's decision regarding nanopesticides and/or nanosilver pesticide products.

Public Comments:

The Environmental Defense Fund supported the petition and commented that if products containing

nanosilver are not properly regulated, their use could result in releases to the environment as well as human exposure that would result in uncertain and possibly unacceptable risks. In addition to comments relative to environmental impact, the Environmental Defense Fund also stated that in addition to surface charges, nanoparticles may also exhibit changes in surface chemistry and electrical conductivity that are the basis for their distinction from bulk material of the same chemical formula. These properties could result in novel toxicological interactions and the hazards associated with nanoscale materials cannot be readily inferred or extrapolated from data pertaining to bulk-scale materials.

A comment from an individual supporting the petition states that the properties that make nanosilver lucrative to manufacturers can be highly destructive to the environment and raise health concerns. The commenter also asserts that the wide range of products that are currently available is creating broad and intrusive exposures to the public and the environment.

The Nanotechnology Citizens Engagement Organization stated that the widespread and uncontrolled use of nanosilver in consumer products is likely to result in increasing levels of silver in the environment, the workplace and in homes. It asserted that it is well known that nanoscale materials can be more toxic because of their high surface-to-volume ratios and their ability to be transported more readily through bodily barriers. Finally, it posited that the government has the responsibility to inform the general public about the potential risks relative to silver and nanosilver.

The concerns expressed by the Bay Area Clean Water Agencies focused on the release of silver into sanitary sewer systems and the potential for increasing silver concentrations in publicly owned wastewater treatment works (POTWs). They further stated that not enough is known about the toxicity, bioaccumulation potential and persistence of nanosilver material and its associated risks. This group also believes that risk assessments should require information about mass loadings to the environment and such information is not currently available.

The National Association of Clean Water Agencies (NACWA) commented that little is known about the environmental impacts of these nanoscale silver products. For instance, they claim that they could add to the silver loads that are already toxic to the environment, they could add to the silver loads that have completely different impacts due to their unique nanoscale size, or they could be relatively harmless. NACWA also commented that the Agency should also determine how nanoscale silver affects the wastewater treatment process.

Purest Colloids, Inc., Crop Life America and The Silver Institute take the position that EPA is exempt from NEPA requirements under FIFRA and cite numerous cases to support this position.

EPA Response:

The Agency is granting the Petitioner's request that EPA require data regarding the effects of nanosilver on human health and the environment. As discussed above, existing data requirements may need to be adapted to assess the risks from use of a proposed pesticide containing a nanosilver ingredient. In addition, EPA will identify products containing nanosilver and will evaluate them in registration review. Further, as requested by the Petitioner, when setting tolerances EPA will continue to comply with the requirements of the FFDCA, as amended by the FQPA, including the consideration of risks to infants and children. The Agency also intends to fulfill its obligations under the ESA in its future regulatory actions. Based on previous case law, however, NEPA procedures do not apply to registration decisions under FIFRA; therefore that portion of the petition is denied. Finally, EPA does not agree that the available data allow EPA to conclude that nanosilver generally poses an unreasonable risk.

As a general matter, the determination of whether a pesticide poses an unreasonable risk involves

consideration of both risks and benefits of the pesticide. Risk, in turn, is a function of the pesticide's toxicity and human and environmental exposure to the pesticide. Because Petitioner references no human health or environmental toxicity data indicating that nanosilver is so inherently toxic that any use of nanosilver would cause unreasonable adverse effects on the environment (and EPA is aware of none), EPA's review of pesticide products containing nanosilver will continue to be based on an assessment of toxicity data in concert with information on the potential exposures to the nanosilver ingredient. Thus, EPA denies Petitioner's request to conclude that all forms and all pesticidal uses of nanosilver generally pose an unreasonable human health or environmental risk.

However, EPA will continue to assess whether use of any pesticide product containing a new nanosilver ingredient causes unreasonable adverse effects on human health, including the health of infants and children, or on the environment, and will continue to take into consideration EPA's and Petitioner's concern that nanosilver may have a different toxicity profile from macro-silver ingredients. EPA's most recent final decision for AGS-20 and proposed decision for NSPW-L30SS present EPA's analysis of these issues under EPA's FIFRA section 3(c)(7)(C) authority. See, HeiQ AGS-20 Final Decision (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2009-1012) and Proposed Decision for Nanosilva NSPW-L30SS (available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2012-0594). In addition, in response to Petitioner's comment to address the "unknowns," EPA acknowledged in each of the reviews noted above some question regarding whether the nanosilver in the proposed products would have the same type or level of toxicity as the nanosilver used in the referenced studies, and, as a result, EPA used an additional uncertainty factor in its risk assessments and required additional data to refine its risk assessments.

Thus, consistent with EPA's recent reviews, EPA expects, in the near term, to continue to consider the data and effects noted above, along with any additional information submitted with the application, any other new available data and all discernible exposure patterns. EPA will also continue to use appropriate uncertainty factors when assessing risks and require additional data, as appropriate, as a condition on the grant of the registration and/or as terms and conditions on the registration. For example, EPA also expects to continue to require more refined product chemistry data and leaching studies to determine the nature and quantity of the silver or nanosilver that is released from any use of the pesticide product. Such information further refines the exposure portion of the risk assessments, including the assessment of potential increased silver loading in the environment from use of a pesticide containing nanosilver, rather than relying on historical exposure assumptions. Finally, EPA also notes, for the foreseeable future, that it will continue to provide public notice of and take comment on proposed decisions for products containing new nanosilver active ingredients, and thus Petitioner and commenters will continue to have an opportunity to influence EPA's review of the data and the proposed decisions regarding the terms of registration.

With respect to Petitioner's request that EPA comply with FFDCA requirements and thus "set a 10-fold margin of safety in setting the nano-silver tolerance and ensure that there is a reasonable certainty that no harm will result from aggregate exposure," EPA notes that it has not yet received a petition for a tolerance or tolerance exemption under the FFDCA to cover residues of nanosilver as a pesticide chemical residue in or on food. Nor has EPA received an application for such food or feed use. For example, the applications received thus far are for pesticide nanosilver products not for use in food contact items. However, should an application or petition be filed, EPA agrees with Petitioner that the FQPA safety standard would need to be considered and met, including the FQPA provisions relating to infants and children.

In the case of NEPA, EPA agrees with the commenters that it is well settled that EPA is exempt from

NEPA requirements under FIFRA. See, e.g., *Merrell v. Thomas*, 807 F. 2d 776 (9th Cir. 1986). EPA does not agree with Petitioner's apparent criticism of the exemption, or the unsupported assertion that NEPA's "general" and programmatic requirements apply, notwithstanding the exemption.

With respect to Petitioner's request regarding compliance with and consultation under the ESA, EPA agrees that it will consider its ESA obligations in the context of new pesticide registrations requests involving nanosilver as an ingredient.

IV. ICTA Requested Action: Take regulatory actions against the class of nanosilver products illegally sold without EPA FIFRA approval, including issuing stop sale, use or removal orders for illegal and unlabeled nanosilver pesticide products

Petitioner:

The Petitioner states that both nanosilver as an active ingredient and nanosilver products are illegal pesticide products, particularly if making public health claims, and that the Agency should act to remove illegal pesticide products by issuing Stop Sale, Use or Removal Orders (SSURO).

Public Comments:

The Environmental Defense Fund stated in support of the ICTA petition that EPA should clarify that pesticidal intent and public health claims can be both implicit and explicit and that manufacturers cannot avoid pesticide classification simply by stripping their products of labeling.

The Copper Development Association commented that many products take advantage of the inconsistent and ambiguous enforcement of the treated articles provision in EPA's regulations (40 CFR 152.25(a)). The Association further urged the Agency to ensure proper regulation of products for which public health claims are made and to require full FIFRA registration including efficacy review.

The American Chemistry Council, who filed comments opposed to the ICTA petition, stated that the Agency should carefully review the product inventory list as supplied in Appendix A of the petition and ensure that products listed, which are identified as products containing nanomaterials, are what they claim to be.

EPA Response:

EPA is denying Petitioner's request to use a particular enforcement strategy to address unregistered pesticides sold or distributed in the United States.

As noted earlier, EPA does not have the factual basis to conclude that all nanosilver products are pesticides and thus does not have the legal basis to conclude that all such products are illegally sold or distributed. Thus, EPA will not commit to take enforcement action against all nanosilver products.

In addition, EPA acknowledges that certain types of products and claims noted in Appendix A have been the subject of enforcement action in the past and continue to be investigated by EPA. However, EPA does not believe it would be appropriate to commit to any particular enforcement action or to comment on any particular case at this time. The appropriateness of any enforcement strategy is subject to many factors, and the Agency needs to maintain the ability to adapt its enforcement strategies as appropriate. Thus, rather than agreeing to a particular enforcement action to address unregistered pesticides containing nanosilver, EPA will continue to use its discretion to determine when or how best to apply its enforcement authorities.

V. ICTA Requested Action: If any nanosilver pesticide registration is approved, EPA should apply all appropriate pesticide requirements to nanosilver pesticides

Petitioner requests that if nanosilver pesticide products are approved, EPA must ensure that the products meet all regulatory requirements including requiring labeling and post-registration notification requirements. The five regulatory actions identified in the petition are discussed below.

A. Nanosilver pesticide products must bear EPA-approved labels.

Petitioner:

Petitioner states that registered nanosilver pesticide products must bear EPA-approved labels, including a proper ingredient statement, directions for use, classification for restricted use and hazard and precautionary statements. Petitioner takes the position that current nano-silver pesticide products are in violation of FIFRA for their commercial sale without proper labeling.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

The Agency agrees with the Petitioner that registered nanosilver pesticides must comply with EPA's labeling requirements. Pesticide products are required to contain warning or caution statements and use directions that are adequate to protect health and the environment. According to the definitions in Sec. 2(q) of FIFRA, any pesticide which fails to contain warnings or cautions that may be necessary to protect the health and the environment would be considered misbranded. The Agency agrees that proper labeling should accompany nanosilver pesticides and has reviewed the labeling with applications for registration of pesticides containing nanosilver to ensure this is the case.

B. EPA should require post-registration notification of adverse effects by the registrants

Petitioner:

The Petitioner notes that registration of nanosilver pesticides places upon registrants a continuing obligation to report to EPA any new factual information the registrant learns about unreasonable adverse effects on the environment from the pesticide.

Public Comments:

Crop Life America stated that once a pesticide is registered, FIFRA provides EPA with the authority to seek additional data or require registrants to submit adverse effects information pursuant to Section 6(a)(2) of FIFRA.

EPA Response:

The Agency agrees with both the Petitioner and Crop Life America. Specifically, FIFRA section 6(a)(2), as implemented through existing regulations in 40 CFR part 159 and at 40 CFR 152.50(f)(3), already imposes an obligation to report information concerning unreasonable adverse effects to EPA, whether as part of the application for registration or post registration. The statute and regulations provide that if, at any time after the registration of a pesticide, the registrant has additional factual information regarding unreasonable adverse effects, the registrant shall submit such information to the Administrator. With respect to existing registrations, compliance with FIFRA section 6(a)(2) and the implementing regulations assures that EPA has access to any information that could be used to determine whether a previous decision to register a product remains a correct decision.

C. Post-registration testing and new data development must be required by the Agency to ensure FIFRA's standards are maintained.

Petitioner:

Petitioner asserts that EPA should require nanosilver registrants to develop new data post-registration.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

The Agency agrees with the Petitioner insofar as the Agency currently has the authority to require, on a case-by-case basis, post-registration testing and new data development. Under FIFRA section 3(c)(2)(B), at any time after initial registration, "if the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person." Failure to respond to such a Data Call-In Notice (DCI) can serve as the basis for suspending the registration of the pesticide, which could impact the ability of the registrant or any other person to sell or distribute the pesticide.

In addition, currently registered pesticides containing silver or nanosilver will be reviewed to determine whether such pesticides continue to meet the standards for registration, and additional data will be required to support those determinations. For example, on July 6, 2012, EPA published in the Federal Register a notice announcing the establishment of the registration review docket (EPA-HQ-OPP-2011-0370) for nanosilver. Along with opening the docket, EPA made a summary document for the registration review of nanosilver available for public comment. The summary document identifies four registrants who have stated that their seven products contain nanosilver and one registrant whose three products are suspected to contain nanosilver. The summary document also contains a preliminary work plan and fact sheet, along with ecological risk assessment problem formulation and human health scoping sections describing scientific analyses and data expected to be necessary to complete nanosilver review.

Finally, as noted earlier, EPA may also require additional data as part of a term and condition if conditionally registering a pesticide product containing a new nanosilver ingredient.

D. Conditional registration can be allowed in order to allow time for the generation and submission of new data.

Petitioner:

Petitioner notes that EPA can conditionally register a pesticide in order to allow time for the generation and submission of new data when the Agency does not have enough data to make an unconditional decision.

Public Comments:

Crop Life America cited conditional registration authority as another example of EPA's broad authority under FIFRA to regulate pesticides containing nanosilver.

EPA Response:

As discussed earlier, EPA agrees with Petitioner and commenters that EPA may issue, where appropriate, conditional registrations for pesticide products containing nanosilver materials.

E. EPA should disclose confidential business information (CBI) in the public interest

Petitioner:

Petitioner states that EPA should disclose all data submitted with registration applications for nanosilver products, including disclosure of data claimed to be CBI, because of the "dearth of information on the risks of nanotechnology" and should disclose under FIFRA section 10(d)(2) information concerning "production, distribution, sale, or inventories of a pesticide in connection with a public proceeding" because the "public interest is benefited from a transparent and open dialog on the risks of any new and emerging technology such as nanotechnology."

Public Comments:

Crop Life America and other commenters opposed this portion of the ICTA petition, asserting that CBI disclosure as urged by Petitioner would require EPA to unlawfully disregard clear statutory requirements.

EPA Response:

EPA agrees with Petitioner about the need for transparency and open dialogue on the risks of any new and emerging technology such as nanotechnology and thus is making available information that is not confidential business information. However, EPA is denying Petitioner's general request to disclose confidential production, sales or inventory data under FIFRA section 10(d)(2).

Confidentiality of information submitted under FIFRA is governed by Section 10 (with additional provisions in Sections 7 and 12). FIFRA section 10(b) bars EPA from disclosing information "which in the Administrator's judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential." FIFRA section 10(d)(1), however, specifically excludes certain safety and efficacy data performed on or with a registered pesticide or its ingredients from the prohibition against disclosure in section 10(b). Safety and efficacy data constitute much of the information provided to EPA to support pesticide registrations, and thus, these and most other types of data are routinely available to the public.

Although EPA agrees with Petitioner about the need for transparency and open dialogue on the risks of any new and emerging technology such as nanotechnology, EPA is denying Petitioner's general request to release certain confidential information under FIFRA section 10(d)(2). There is no public proceeding necessitating the public interest finding for the release of the requested information, but more importantly there is no need to disclose the requested information. Such information is not necessary for the public to evaluate the risks from use of proposed pesticides as EPA initiated a program for transparency and public participation in the registration process in 2009. See http://www.epa.gov/pesticides/regulating/public-participation-process.html. As a result of this program, proposed registration decisions for certain types of pesticide applications (as specified below) will be placed in the docket and open for public comment prior to issuance of the registration decision. Such proposed decisions typically include EPA's review of safety and exposure data, EPA's review of any efficacy data, EPA's estimates and assumptions relating to potential exposures, and the assessment of all of the above in determining whether there is a risk concern. Responses to any comments filed are also publicly available in the docket. This public participation process applies to new active ingredients and to first food, first outdoor, and first residential uses for already-registered active ingredients, so safety and exposure data supporting an application to register products containing new nanosilver ingredients will be available for public review and comment prior to registration decisions on such an application. For example, EPA announced and invited public comment on its proposal to approve the conditional

registration of a nanosilver product. See, e.g., http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/nanosilver.html EPA also made the reviews and analyses on which its proposal relied available in a public docket at www.regulations.gov in Docket ID # EPA-HQ-OPP-2012-0594.

VI. ICTA Requested Action: Take other EPA FIFRA actions necessary for adequate oversight of nanosilver pesticides, including:

In addition to the Agency actions discussed in previous sections of this response, the Petitioner is requesting that EPA use all other relevant FIFRA oversight mechanisms to address the potential environmental and human health impacts of nanosilver and determine whether nanosilver presents an unreasonable risk to man or the environment. The seven additional regulatory mechanisms suggested by Petitioner are discussed, in turn, below.

A.Undertaking a classification review of nanosilver pesticides

Petitioner:

Petitioner states that EPA should undertake a classification review of nanosilver pesticides based on the environmental impacts of nanosilver and the existing unknowns associated with the safety of nanosilver.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

EPA agrees with Petitioner that it may be appropriate in some cases, as part of a registration decision, to consider whether to evaluate a pesticide against the classification criteria and provisions in 40 CFR 152.170 and 152.171 but has not yet deemed such evaluation or classification necessary for the nanosilver applications it has received.

EPA regulations at 40 CFR 152.170 and 152.171 authorize EPA, in its discretion and after application of the regulatory criteria, to determine that a pesticide is best managed through classification as a restricted use pesticide, which is to say that the product may only be used by certified applicators or individuals under their direct supervision. The decision to initiate consideration of a restricted use classification is in EPA's discretion and any decision to classify a product for restricted use would depend on the characteristics of the particular product and proposed uses. EPA has not yet identified a need for such evaluation or classification with respect to the recently considered applications for registration of nanosilver ingredients.

B.Undertaking a Special Review of nanosilver pesticides

Petitioner:

Petitioner states that EPA should undertake a Special Review of nanosilver because it poses environmental risks that meet the criteria for initiation of a Special Review as set forth in 40 CFR 154.7(a).

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

EPA is denying Petitioner's requested action on this issue. The Special Review process is a framework

for evaluating a currently-registered product when the Agency discovers that the use of the product may result in unreasonable adverse effects on people or the environment. It usually involves intensive review of only a few or just one potential risk concern, and provides for significant public participation and transparency. The review involves evaluating existing data, acquiring new information and/or studies, assessing the identified risk, and determining appropriate risk reduction measures.

While the Special Review process provides a mechanism for public feedback, EPA has learned after many years of experience conducting Special Reviews that the Special Review process often results in unnecessary delays in Agency action. Thus, while EPA does not anticipate initiating a Special Review of nanosilver, the Agency will ensure that the key elements of the process – a careful and transparent consideration of the science issues that incorporates public participation – are present in EPA's evaluation of applications to register new nanosilver products. Specifically, as noted above, EPA initiated an informal process in 2009 to increase transparency and public participation in the registration process. Because of this program, the public can now review and comment on the risk assessments and proposed registration decisions on new pesticide active ingredients, and on the first food use, first outdoor use, and first residential use for currently registered active ingredients. Finally, in addition, as noted earlier in this response, pesticides containing silver and nanosilver ingredients will be evaluated in registration review.

C.Requiring the submission of nano-specific data from nanosilver applicants

Petitioner:

Petitioner states that EPA should require from prospective nanosilver registrants the data necessary to perform its risk assessments.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

EPA agrees that data necessary to perform risk assessments and to support registrations of pesticide products containing nanosilver ingredients should be required. This is what EPA routinely does and will plan nothing different for pesticides containing nanosilver, whether as part of a registration decision or in registration review. EPA must thoroughly evaluate pesticides proposed for registration to ensure that they meet the requisite statutory standards and EPA grants a registration only after determining that these statutory findings are met. Therefore, as requested by Petitioner and discussed elsewhere in these responses, prospective nanosilver registrants are required to develop and submit (or cite) to studies to meet the necessary data to support registration of new nanosilver products.

D.Amending FIFRA regulations to require nanosilver specific data

Petitioner:

Petitioner states that EPA should amend its regulations to require data specifically conducted with nanosilver materials to support registrations for pesticides containing such material. Petitioner notes that current data requirements for product composition, certified limits, and physical and chemical characteristics do not address information regarding some of the key unique properties of nanomaterials. Petitioner further notes that there is a well-established precedent for actions amending data requirements for specific types of pesticide products, and provide the example of EPA's promulgation of specific data requirements for genetically modified microbial pesticides.

Public Comments:

The Environmental Defense Fund joined Petitioner in calling for EPA to amend its regulations to require nano-specific environmental health and safety data for nanopesticides such as nanosilver. Crop Life America countered that FIFRA provides EPA with broad authority to regulate nanopesticides and that amending the regulations are not necessary.

EPA Response:

While EPA shares Petitioner's concerns that nanosilver may have unique properties that affect the safety of its use in pesticide products, EPA is denying Petitioner's requested action on this issue at this time. As discussed in section II of this response, EPA has concluded that it generally will need additional data to assess the potential effects of pesticides containing nanosilver ingredients. However, EPA has been addressing data needs on a case-by-case basis, in the context of individual registration actions and in its review of existing registrations. Because FIFRA authorizes EPA to require additional data as appropriate to ensure that use of a proposed pesticide or a currently registered pesticide meet and continue to meet registration standards, EPA concludes there is no need to initiate rulemaking at this time.

E.Performing registration review of existing bulk silver pesticide registrations

Petitioner:

Petitioner states that EPA should undertake a registration review for existing registered products containing silver, in order to consider and analyze the new scientific issues of nanotechnology and nanosilver.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

EPA agrees with Petitioner and has already started this process. On June 24, 2009, EPA announced the opening of the registration review docket for silver and its compounds [74 FR 30070]. The registration review preliminary workplan for silver and its compounds (cases 4082 and 5015) is available through the docket at www.regulations.gov in Docket ID # EPA-HQ-OPP-2009-0334. The comment period on the preliminary workplan closed on September 22, 2009. EPA reviewed and responded to the comments, and published the final workplan on December 30, 2009.

As discussed in the final workplan, the Agency needs additional data for its human health risk assessments, as well as new studies to support its assessment of environmental fate, ecological effects, and endangered species risks. Data call-ins requiring the submission of these data by current silver manufacturers were issued on February 29, 2012.

Prior to beginning registration review for silver, the Agency determined silver zeolites would require a different data set based on the presence of chemicals within the zeolite moiety which alter the toxicology profile of silver. Zeolite forms of silver will therefore not be covered under the registration review for silver. In addition, products containing silver in nanoform will also be evaluated using a data set that is specific to this technology and are not included in the registration review work plans for silver. However, the DCI for silver and silver compounds issued on February 29, 2012, required submission of particle size data. EPA is currently reviewing the particle size data and may determine that some of the products covered by the silver and silver compounds case and DCI should also be included in the nanosilver registration review case.

F.Regulating nanosilver devices

Petitioner:

Petitioner states that if EPA determines that one or more of the nanosilver products should be classified as a pesticide device rather than a pesticide, the Agency should ensure each complies with FIFRA's pesticide device requirements, including accurate labeling.

Public Comments:

Crop Life America cited the Agency's classification of the Samsung Silvercare™ washing machine as a pesticide device and example of the enforcement mechanisms available under FIFRA.

EPA Response:

EPA agrees with Petitioner that if a product is a device and not a pesticide subject to registration, the device statutory and regulatory provisions will apply for such device. A pesticide device is defined in FIFRA as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man or other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom." [FIFRA section 2(h)] The key distinction between pesticides and devices is whether the pesticidal activity of the article is due to physical or mechanical actions (device), or due to a substance or mixture of substances (pesticide). Some of the types of products that are typically considered devices, not pesticides, are ultra violet light systems, water and air filters (except those containing substances or mixtures of substances that act upon a pest), and ultrasonic devices making claims to inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites.

As provided in 40 CFR 152.500, pesticide devices are not required to be registered under FIFRA section 3, but they are subject to other requirements, including establishment registration, recordkeeping, inspection, and import-export requirements, but not to most labeling requirements of the sort typically found on pesticide products. As requested by Petitioner, if EPA determines that any products containing nanosilver are pesticide devices rather than pesticides, those products will be subject to the requirements for pesticide devices.

In September 2007, EPA published a Federal Register notice clarifying its position on the distinction between devices and pesticides with regard to ion generators that incorporate a substance (e.g., silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (e.g., bacteria or algae) [72 FR 54039]. An example of this type of product is the Samsung Silver Care Washing Machine referenced in the ICTA petition. Because ion generators like the Samsung washing machine incorporate a substance or substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution. This requirement holds regardless of whether the substance or substances accomplishing the pesticidal purpose are macroscale- or nanoscale-sized materials. Note, however, contrary to Crop Life's comment, EPA has not determined that washing machines are generally classified as devices.

G.Set a pesticide tolerance for nanosilver

Petitioner:

Petitioner requests that EPA set a pesticide tolerance for nanosilver, noting that nanosilver residues may be present in food or animal feed due to migration from containers or processing equipment.

Public Comments:

The Agency did not receive specific comments on this issue.

EPA Response:

EPA is neither granting nor denying Petitioner's requested action because there are currently no registered nanosilver pesticides with food or feed uses. However, consistent with FIFRA 3(c) and 2(bb), if the Agency receives an application for a proposed use of pesticide containing nanosilver and determines that use of such product necessitates a tolerance or exemption from the requirement of a tolerance, EPA will not register that product until it has taken appropriate action under section 408 of the FFDCA.