



December 8, 2008

Via electronic filing
Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Re: Petition for Rulemaking by International Center for Technology Assessment *et al.*; Registration of Nanoscale Silver Products under FIFRA. 73 FR 69644; November 19, 2008; Docket Number EPA-HQ-OPP-2008-0650.

Dear Sir or Madam:

CropLife America (CLA), the nation's largest trade organization for promoting the safe and responsible use of crop protection products and its industry, is pleased to submit the following comments on the petition for rulemaking filed with U.S. Environmental Protection Agency (EPA) Administrator Stephen L. Johnson by the International Center for Technology Assessment (ICTA) on May 1, 2008, as requested in 73 FR 69644 (11/19/2008).¹ Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute virtually all of the crop protection and biotechnology products used by American farmers. CLA recognizes the importance of the issues EPA has been asked to consider, and welcomes this opportunity to provide comment so that EPA may consider these views as it formulates its response.

¹ ICTA, "Citizen Petition for Rulemaking to the United States Environmental Protection Agency -- Petition for Rulemaking Requesting EPA Regulate Nano-Silver Products as Pesticides" (ICTA Petition), available at http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition_final_5_1_08.pdf.

The ICTA Petition, which ICTA filed on behalf of itself and 13 other petitioners,² requests that EPA regulate as pesticides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and that EPA take additional actions under FIFRA and other environmental statutes with respect to, products containing nanoscale silver. The petitioners specifically request that EPA take the following steps: clarify that nanoscale silver and nanoscale silver products are pesticides requiring registration under FIFRA; determine that nanoscale silver is a new pesticide (*i.e.*, a new active ingredient) requiring a new pesticide registration; assess the potential human health and environmental risks of nanoscale silver under FIFRA, the Food Quality Protection Act, the Endangered Species Act, and the National Environmental Policy Act (NEPA); take immediate action, including the issuance of Stop Sale, Use or Removal Orders, to stop the sale of illegal nanoscale silver pesticide products; fully apply all FIFRA pesticide requirements in the event EPA registers any nanoscale silver products; and take other actions necessary for adequate EPA oversight of nanoscale silver pesticides.³

CLA does not share the apparent view of the petitioners that current EPA policies and procedures are inadequate to regulate any nanoscale products that may be pesticides or that the broad remedies requested are necessary or appropriate. CLA urges EPA to deny the ICTA Petition since EPA, through its authority under FIFRA to address the research and development (R&D), registration, post-registration, and enforcement of pesticides, can accommodate any issues that may arise with respect to specific nano-products and their potential regulation as pesticides.

FIFRA Provides EPA with Broad Regulatory Authority to Regulate Pesticides, Including Nanopesticides, and Sweeping Changes in FIFRA’s Regulations Are Not Warranted or Necessary

In its Petition, ICTA argues that EPA needs a “new strategy” for addressing nanopesticides.⁴ CLA disagrees. CLA supports the view conveyed to then-EPA General Counsel Ann Klee and other EPA officials and staff in mid-2006 by the American Bar Association’s Section of Environment, Energy, and Resources (ABA SEER) that “EPA has considerable authority under FIFRA to prohibit, condition, or allow the manufacture and use of nanopesticides.”⁵ As explained by the ABA SEER team:

² The other petitioners include: The Center for Food Safety; Beyond Pesticides; Friends of the Earth; Greenpeace; The Action Group on Erosion, Technology and Concentration; Center for Environmental Health; Silicon Valley Toxics Coalition; Institute for Agriculture and Trade Policy; Clean Production Action; Food & Water Watch; Loka Institute; The Center for the Study of Responsive Law; and Consumers Union.

³ ICTA Petition at 28-114.

⁴ *Id.* at 26.

⁵ ABA SEER, *The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides*, at 4 (May 2006) (ABA SEER Paper), available at

[EPA's] regulatory tools include regulation of pre-registration research and development (R&D) through experimental use permits (EUPs); requirements for pre-registration testing; the registration requirement, which requires development of data and can [lead to] limits on the use and handling of a nanopesticide; requirements for registrants to submit post-registration adverse effects information; possible requirements for post-registration testing; and reregistration requirements.⁶

FIFRA as currently implemented is well-suited to address the issues raised by nanomaterials that may have pesticidal uses. EPA, for example, has authority under its experimental use permit (EUP) regulations to ensure that any pesticide used in certain R&D applications does not impose risks on the environment.⁷ This authority extends to FIFRA's registration process, which is an extensive process and can result in the submission of substantial data or the imposition of appropriate restrictions to ensure that a pesticide product will not cause any "unreasonable adverse effects on the environment."⁸ FIFRA also provides EPA with continuing authority once a pesticide is registered to seek additional data or require registrants to submit, under FIFRA Section 6(a)(2), adverse effects information.⁹ EPA itself acknowledges the

<http://www.abanet.org/envIRON/nanotech/pdf/FIFRA.pdf>. CLA notes as well that the President's Office of Science and Technology Policy (OSTP) and Council on Environmental Quality (CEQ) maintain that "existing statutory authorities are adequate to address oversight of nanotechnology and its applications." OSTP and CEQ, "Memorandum for the Heads of Executive Departments and Agencies: Principles for Nanotechnology Environmental, Health, and Safety Oversight" (Nov. 8, 2007), available at http://www.ostp.gov/galleries/default-file/Nano%20EHS%20Principles%20MemoOSTP-CEQ_FINAL.pdf.

⁶ ABA SEER Paper at 4.

⁷ FIFRA § 5, 7 U.S.C. § 136c; 40 C.F.R. § 172.2 ("any person wishing to accumulate information necessary to register under section 3 of the Act and the regulations thereunder (1) a pesticide not registered with this Agency or (2) a registered pesticide for a use not previously approved in the registration of the pesticide may apply to the Administrator at any time for an experimental use permit").

⁸ FIFRA § 3(a), 7 U.S.C. § 136a(a).

⁹ FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B) ("[i]f 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"); FIFRA § 6(a)(2), 7 U.S.C. § 136d(a)(2) ("[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator").

ability of FIFRA to address issues related to potential nanopesticides when it states: “FIFRA and EPA’s implementing regulations provide an effective framework for regulating pesticide products that are a product of nanotechnology or that contain nanoscale materials.”¹⁰

The ICTA Petition, however, attempts to introduce new or more onerous registration requirements for nanosilver products that are not warranted or necessary. Under the statutory registration process, EPA can register a product if it determines that the product does not cause “unreasonable adverse effects on the environment.” EPA, through its existing regulations and guidance regarding the registration of pesticides, is capable of making this determination for products that utilize nanotechnology. In its Petition, ICTA attempts to substitute its judgment for that of EPA’s in determining when a pesticide can be registered and to override well established statutory and regulatory requirements to impose more onerous registration requirements for nanosilver than any other pesticide. Specifically, ICTA states that the “approval of a pesticide is contingent on an agency determination that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5), including *inter alia*, the determination that the product will not cause unreasonable adverse effects on the environment.”¹¹ ICTA goes on to state “to ensure it has all the data it needs on nano-silver to perform the risk assessments, EPA should require the necessary data from prospective registrants for nano-silver products.”¹²

The applicable requirements in FIFRA and its implementing regulations and EPA policies apply equally to all registered pesticide products irrespective of what the active ingredient in a particular product is. EPA can make these determinations, as it should for all pesticides, based on its own review and not based on the judgments expressed in any petition. Moreover, under EPA’s regulations, EPA can decide to register a nanopesticide under FIFRA Section 3(c)(7), which allows EPA conditionally to register a pesticide when EPA does not have sufficient data to make an unconditional registration decision under FIFRA Section 3(c)(5).¹³ ICTA acknowledges later in its Petition that EPA does have authority to issue conditional registrations,¹⁴ and in fact most registrations granted are conditional.

EPA should deny any aspect of this Petition that would attempt to assert more onerous criteria for registration of nanosilver products than those imposed for all other pesticides. FIFRA establishes one uniform legal standard for registration of all pesticides, and EPA is capable of

¹⁰ EPA, *Pesticide issues in the works: nanotechnology, the science of small* (July 22, 2008), available at <http://www.epa.gov/pesticides/about/intheworks/nanotechnology.htm>.

¹¹ ICTA Petition at 73.

¹² *Id.* at 74.

¹³ 40 C.F.R. §§ 152.111-114.

¹⁴ ICTA Petition at 102.

addressing any issues that may arise in applying this standard to particular products as part of the normal registration process. If EPA determines that it needs particular types of data to determine whether or not a particular nanopesticide or group of nanopesticides meets the standard for registration, it has adequate authority to require and to consider such data.

CLA also objects to ICTA's assertion that EPA must prepare a programmatic environmental impact statement (EIS) under NEPA before "enacting, adopting, or amending its regulations to create a regulatory program for nano-silver pesticide regulation, and before continuing to act under its regulatory program on nano-silver pesticide regulation."¹⁵ As discussed above, there is no reason for EPA to enact any new or amended regulations to govern registration of nanosilver pesticides. In any case, there is no circumstance where an EIS would be required prior to registering any pesticide or group of pesticides, or prior to establishing a policy concerning registration of any pesticide or group of pesticides.

Courts have long held that compliance with NEPA would be redundant and is not required for actions under certain environmental statutes where the statutory process is "functionally equivalent" to the NEPA process. Indeed, the first application of this doctrine involved registration of pesticides under FIFRA. In *Environmental Defense Fund v. EPA*, the D.C. Court of Appeals held that EPA did not need to prepare an EIS before cancelling most uses of DDT because the required analysis was "functionally equivalent" to the analysis required under NEPA.¹⁶ Other cases subsequently applied this same doctrine to the decision by EPA to cancel certain predator control agents¹⁷ and to the decision by EPA to grant an emergency exemption under FIFRA Section 18.¹⁸ More recently in *Merrell v. Thomas*, the Ninth Circuit Court of Appeals rejected an argument that EPA was required to prepare an EIS before granting certain pesticide registrations because the detailed process in FIFRA for considering the environmental impacts of pesticides effectively supplants the process for evaluating other federal actions under NEPA.¹⁹ In affirming summary judgment in favor of defendants, the court stated:

To apply NEPA to FIFRA's registration process would sabotage the delicate machinery that Congress designed to register new pesticides. It would increase a regulatory burden that Congress

¹⁵ *Id.* at 96.

¹⁶ *Environmental Defense Fund v. EPA*, 489 F.2d 1247, 1254-56 (D.C.Cir.1973).

¹⁷ *Wyoming v. Hathaway*, 525 F.2d 66, 71-72 (10th Cir.1975), *cert. denied*, 426 U.S. 906 (1976).

¹⁸ *Environmental Defense Fund v. Blum*, 458 F.Supp. 650, 661-62 (D.D.C.1978).

¹⁹ *Merrell v. Thomas*, 807 F.2d 776 (9th Cir. 1986).

intentionally lightened in 1978 and create new opportunities for litigation where litigation was recently quelled.²⁰

In addition, CLA objects to the ICTA Petition's claim that disclosure of any claimed confidential business information (CBI) regarding nanotechnology "is in the public interest because of the dearth of information on the risks of nanotechnology."²¹ Such an action would require EPA to disregard clear statutory requirements, something EPA cannot lawfully do, nor is there any need for EPA to do so. Indeed, petitioner's argument could potentially be made with respect to many new pesticidal active ingredients. Yet, Congress clearly drew a balance in enacting FIFRA that differs from the policy the petitioners now wish to impose.

Specifically, Congress carefully drafted FIFRA Section 10 to balance the legitimate interest of commercial enterprises in protecting CBI and trade secret information and the public interest in allowing access to the health and safety data supporting registration decisions. FIFRA Section 10(b)²² generally protects trade secret or commercial or financial information submitted by an applicant from public release, subject to the limitations in FIFRA Section 10(d). FIFRA Section 10(d)²³ requires EPA to make health and safety data publicly available, but also establishes three exceptions.²⁴ EPA cannot disclose any information in these three excepted categories unless it determines that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

If EPA intends to disclose any information that an applicant or registrant contends is exempt from disclosure, EPA must notify the data submitter by certified mail of its intent to release the data, and provide the data submitter with a 30-day period in which to take action in district court to enjoin the release of the information.²⁵ EPA regulations also set forth detailed procedures for evaluating CBI claims if a Freedom of Information Act (FOIA) request is made; if a claim of confidentiality is denied, that is considered a final agency action subject to judicial

²⁰ *Merrell v. Thomas* at 779.

²¹ ICTA Petition at 103.

²² 7 U.S.C. § 136h(a).

²³ 7 U.S.C. § 136h(b).

²⁴ FIFRA § 10(d)(1), 7 U.S.C. § 136h(d)(1). These exceptions are: (1) data concerning pesticide manufacturing or quality control processes; (2) the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient in a pesticide product; and (3) the identity or percentage quantity of any deliberately added pesticide inert ingredient.

²⁵ FIFRA § 10(c), 7 U.S.C. § 136h(c); FIFRA § 10(d)(3), 7 U.S.C. § 136h(d)(3).

review.²⁶ EPA's CBI provisions under FIFRA thus are very specific regarding the information that can be disclosed and those determinations regarding the disclosure of CBI that must be made on a case-by-case basis.²⁷ CLA urges EPA to deny any portion of the ICTA Petition that attempts to subvert the existing statutory requirements established by FIFRA Section 10, or the related procedures and practices established by regulation which govern the disclosure of claimed CBI.

FIFRA's Enforcement Mechanisms Are Adequate to Address Any Pesticide Issues

The enforcement tools available to EPA under FIFRA are entirely adequate to address with any potential misconduct involving pesticides, whether it involves nanotechnology or not. EPA has the authority under FIFRA Section 14 to assess civil penalties or bring criminal charges against a registrant, applicant, or producer who knowingly violates any provision of FIFRA.²⁸ EPA also has the authority under FIFRA Section 13(a) to issue "stop sale, use, or removal" orders to prevent the sale, distribution, or use, or require the removal of a pesticide that is in violation of FIFRA.

There are many examples of the Office of Pesticide Programs' (OPP) significant outreach regarding the need for FIFRA registration for pesticidal claims made in connection with silver or any other antimicrobial. Indeed, the ICTA Petition itself reviews in detail the history of EPA policy on the application of FIFRA registration requirements to the Samsung Silvercare™ washing machine.²⁹ EPA ultimately decided that ion-generating devices that are used for pesticidal purposes must be registered as "pesticides" rather than "devices" under FIFRA.³⁰ The petitioners claim that the decision of EPA not to predicate this policy decision on assertions that the Samsung product utilizes nanotechnology "defies rationality," and that this notice should have addressed the applicability of FIFRA registration requirements to nanomaterials.³¹ In contrast, this EPA policy statement was balanced, factually supported, and well-reasoned. EPA did not need to address or resolve the question of whether conventional chemistries like metallic ions in solution should be construed as a form of nanotechnology to establish its policy

²⁶ 40 C.F.R. § 2.205(f)(1),(2).

²⁷ FIFRA § 10, 7 U.S.C. § 136h; 40 C.F.R. Part 2, subpart B; 40 C.F.R. §§ 2.307, 2.308 (special rules concerning information obtained under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA)).

²⁸ FIFRA § 14(b), 7 U.S.C. § 136l(b).

²⁹ ICTA Petition at 20-25.

³⁰ EPA, Pesticide Registration; Clarification for Ion-generating Equipment, 72 Fed. Reg. 54039 (Sept. 21, 2007).

³¹ ICTA Petition at 24.

concerning antimicrobial ion generators, and EPA's decision on the matter demonstrates that the existing FIFRA registration process works well.

FIFRA Allows EPA to Consider Issues Specific to Particular Active Ingredients

FIFRA allows EPA to consider issues specific to particular active ingredients. EPA has previously recognized FIFRA's breadth when it determined that bioengineered microbial products and plant incorporated pesticides could be regulated under FIFRA without additional legislative authority. Nanopesticides are equally susceptible to regulation under FIFRA without additional legislative authority. Many of EPA's implementing FIFRA regulations and requirements are intended to be applied in a product-specific manner, and EPA has ample authority to obtain any data deemed necessary for it to make the determinations necessary to register or reregister nanopesticide products.

ICTA also argues that EPA should clarify that pesticidal intent "can be shown by means far broader than just labeling."³² There are, however, ample regulations and guidance by EPA explaining when a substance is a "pesticide" that is regulated by FIFRA, and CLA sees no reason to support ICTA's assertion that any clarifications are necessary. It is well-known that the term "pesticide" is defined broadly under FIFRA and that the tests set forth in EPA's regulations for determining when a product must be registered as a pesticide focus on whether pesticidal claims are made for the substance and whether the substance is intended to, or will have, a pesticidal use.³³ A product's claims, or intended uses, can be evaluated under EPA's standard tests for identifying pesticides. There is no reason why the mere fact that a product utilizes or claims to utilize nanotechnology should change in any way the analysis for determining whether that product is a pesticide that must be registered under FIFRA.

FIFRA's Treated Article Exemption Applies to Any Pesticide, Whether Conventional or Based in Nanotechnology, That Meets the Necessary Criteria

EPA regulations include an exemption from pesticide registration requirements for certain "treated articles or substances."³⁴ In general, a product does not have to be separately registered if it is treated with a pesticide registered by EPA, and the purpose of the treatment is to protect the product itself. EPA described its policy concerning the applicability of this exemption from registration requirements in EPA Pesticide Registration (PR) Notice 2000-1,³⁵

³² ICTA Petition at 35.

³³ 40 C.F.R. § 152.15(a)-(c).

³⁴ 40 C.F.R. § 152.25(a).

³⁵ EPA, PR Notice 2000-1, *Applicability of the Treated Articles Exemption to Antimicrobial Pesticides* (Mar. 6, 2000), available at http://www.epa.gov/PR_Notices/pr2000-1.pdf.

and subsequently issued a fact sheet on the same topic.³⁶ EPA has made it very clear that this policy does not apply to any public health claims for human pathogens. Nevertheless, it is also clear that this exemption can apply to claims that a pesticide will inhibit mildew growth on an article, prevent spoilage of the article, or inhibit offensive odors.

In its Petition, ICTA broadly claims that the treated article exemption does not apply to nanosilver.³⁷ ICTA sets forth in Appendix A to the Petition a list of “nano-silver consumer products,” that do not, according to ICTA, qualify for the treated article exemption. An examination of Appendix A indicates that ICTA has not demonstrated that many of these products are even being marketed in the United States. In any case, CLA notes that some of the claims made for the products listed in Appendix A to the ICTA Petition are the type of claims that may be permissible under the “treated article” exemption if the product in question has been treated with a biocide registered by EPA. Thus, EPA may need to determine both whether the “nanosilver” products which particular items have been treated with are registered by EPA, and also whether the claims made for the treated article involve human pathogens or are otherwise deemed to be pesticidal claims under the applicable EPA policy. Ultimately, this exercise is the same regardless of whether nanomaterials or other pesticidal active ingredients have been used, and the enforcement tools available to EPA under FIFRA and the applicable implementing regulations are adequate to identify, prevent, and punish any violations. CLA would urge EPA to reject ICTA’s blanket assertions that certain treated products do not qualify for the treated article exemption, and instead employ a case-by-case analysis for any pesticide, whether conventional or based on nanotechnology, used to treat a product to determine the applicability of this exemption.

CLA appreciates the opportunity to comment on the ICTA Petition.

Sincerely,



Douglas T. Nelson
Senior Vice President
CropLife America

³⁶ EPA, “Consumer Products Treated with Pesticides” (Aug. 2003) (2003 Fact Sheet), available at <http://www.epa.gov/pesticides/factsheets/treatart.htm>.

³⁷ Petition at 41-42.