



Chemical Producers & Distributors Association

*1730 Rhode Island Avenue, N.W.
Suite 812
Washington, D.C. 20036
202.386.7407
FAX: 202.386.7409*

August 17, 2011

[VIA WWW.REGULATIONS.GOV](http://WWW.REGULATIONS.GOV)

Mr. Jed Costanza
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment; 76 Fed. Reg. 35383 (June 17, 2011); Proposed Policy Statement; EPA-HQ-OPP-2010-0197.

Dear Mr. Costanza:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the above-referenced draft document (“Policy Statement”). We are the primary advocate on federal legislative and regulatory issues for generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors.

The U.S. Environmental Protection Agency (“EPA” or “Agency”) proposes to establish a policy for obtaining information about certain defined nanoscale materials that may be present in currently registered pesticide products, and for treating all registration applications for such materials as applications for “new” active or inert ingredients because they are presumptively

“potentially different” than any currently registered non-nanoscale or nanoscale ingredient. Applicants can rebut this presumption and may be able to obtain a “me-too” registration by submitting data and/or other information that demonstrates the nanoscale form has properties “identical or substantially similar” to those of currently registered non-nanoscale or nanoscale forms, or that differ only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment.

CPDA understands EPA’s pressing need to address the use of nanoscale materials in pesticide products and generally supports the use of policy guidance in lieu of regulation at this stage of the Agency’s understanding of these materials. However, we remain concerned about the potential negative impacts on the nanotechnology industry generally and the pesticide industry, in particular, of EPA’s preference for using FIFRA¹ section 6(a)(2) adverse effects reporting to obtain information about the presence of nanoscale materials in pesticides. We are also concerned about the potential financial barrier to commercializing pesticides using nanotechnology that is likely to occur if the Agency uses a rebuttable presumption to categorize all applications involving nanoscale ingredients as applications for “new” active or inert ingredients.

Definition of “Nanoscale Material”

For purposes of the Policy Statement, EPA “describes” (i.e., does not formally “define”) the term “nanoscale material” as “an active or inert ingredient and any component parts thereof intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers (nm).”² Thus, this broad working definition focuses only on the materials’ size and production process and not on any of its unique properties. Although the Policy Statement appropriately excludes incidental production of nanoscale material within the defined size range, it neither provides guidance on how the proposed numerical definition of nanoscale would relate to currently registered nanoscale products nor provides a basis for composition comparisons. We also note that EPA introduces significant uncertainty in making compliance and enforcement decisions by using the term “approximately” to modify the jurisdictional range of nanoscale materials covered by the Policy Statement. Therefore, we recommend that the

¹ FIFRA §§ 2 et seq.; 7 U.S.C §§ 136 et seq.

² Policy Statement at 35384.

Agency use only the specified numerical range of 1-100 nm to describe the nanoscale materials at this time.

The Agency also clarifies that it does not intend this “description” to cover “biological materials (e.g., DNA, RNA, proteins) or materials in their natural state (e.g., clays).”³ CPDA supports this exclusion; however, we recommend that EPA further strengthen the example list of excluded biological materials by adding “enzymes and microorganisms” to the list. Although the existing list includes proteins, and enzymes are primarily proteins, some enzymes are proteins plus “cofactors” that are not proteins and we believe all “enzymes” should be excluded from the “description” of nanoscale materials. In addition, the term “microorganisms” clarifies that more than “chemicals” are included in the term “biological materials.” Thus, the example should read: “biological material (e.g., DNA, RNA, proteins, enzymes, and microorganisms).”

Gathering Adverse Effects Information

EPA’s stated goal in the Policy Statement is to identify what nanoscale materials are in which pesticide products.⁴ To achieve that goal, the Agency proposes to obtain information on such materials using its authority under either FIFRA section 6(a)(2) or section 3(c)(2)(B), with an expressed preference for using section 6(a)(2).⁵ Using section 6(a)(2) would require all registrants to submit specified factual information about nanoscale materials because the Agency believes such information is relevant to and may aid in its ability to determine whether a pesticide may cause unreasonable adverse effects on the environment. As EPA is well aware, the pesticide industry and others have strongly expressed their concerns about the stigma such information gathering under section 6(a)(2) could have on the nanotechnology industry generally and the pesticide industry in particular.

Despite EPA’s clarification that the Agency “is not making a judgment that the presence of any particular nanoscale material poses a risk” and that information other than actual “adverse effects” must also be reported under section 6(a)(2), the general public is not aware of such distinctions. For instance, the phrases “section 6 adverse effects reporting” and “FIFRA adverse

³ Id. at 35387.

⁴ Id. at 35391.

⁵ Id. at 35384.

effects reporting” are commonly used to describe section 6 obligations. In addition, using section 6(a)(2) to obtain information on nanoscale materials in pesticides could also result in mischaracterization of the reason why the information was submitted. For instance, plaintiffs in tort lawsuits involving drift of pesticides containing nanoscale materials to non-target areas would likely allege that EPA had identified those pesticides/materials as causing or being associated with unreasonable adverse effects on the environment. Nanotechnology is a relatively new commercial endeavor, especially for the pesticide industry, and the potential for a product to be stigmatized simply because the Agency is seeking information on the presence of nanoscale materials in registered products is unwarranted.

CPDA believes the Agency should use other FIFRA authority to obtain such information. We especially support EPA’s suggested possible use of a variation on the data call-in (“DCI”) authority of FIFRA section 3(c)(2)(B), which would remove the stigma concerns about using section 6(a)(2) and minimize the information collection burdens on EPA and registrants. As the Agency suggests in the Policy Statement,⁶ EPA could use a more targeted DCI approach, which would not require a response from DCI recipients who either do not have or do not know they have nanoscale materials in their products, and could also focus initial data gathering only on pesticide classes that are most likely to or are known to contain nanoscale active or inert ingredient material (e.g., heavy metals). Future case-by-case registrant/product DCIs could then be used to obtain any subsequently needed data. Therefore, CPDA urges EPA to further explore this phased approach under the DCI provisions of FIFRA, which would ensure the Agency receives the nanoscale “presence,” “process” and “type” information about nanoscale materials in registered products while avoiding the potential for an “adverse effects” stigma. The Agency could then call in new data, as needed, to conduct case-by-case adverse effects assessments for decisions regarding the continued registration of targeted products containing nanoscale materials.

Presumption of “New” Active or Inert Ingredients

⁶ Id. at 35391.

When a nanoscale registration application relies on a comparison to a currently registered product that contains either a non-nanoscale version of the ingredient or a nanoscale version with different characteristics, EPA does not intend to make the required unreasonable adverse effects registration approval decision unless it is based on “specific information on the nanoscale material included in a pesticide product.”⁷ Therefore, EPA proposes to classify any application for registration of a pesticide product containing a nanoscale active or inert ingredient as an application for a “new” active or inert ingredient based on a presumption that the ingredients are not “identical or substantially similar”⁸ to an existing non-nanoscale or nanoscale registered product. However, an applicant could rebut this presumption by providing the Agency with “sufficient” data or information that demonstrates substantial similarity “to EPA’s satisfaction” in order to qualify as a “me-too” registration.

CPDA is concerned that this policy of classifying ingredients based on a “newness presumption” will effectively require all pesticide registrants and ultimately inert ingredient manufacturers to incur significantly higher PRIA⁹ fees and experience much longer review timelines.¹⁰ The Agency admits that it does not have the registration experience with nanoscale materials needed to develop specific data requirements, which would leave applicants having to generate an unspecified type and amount of “sufficient” data to rebut the presumption of newness or satisfy the safety evaluation needed for a “new” active or inert ingredient. Thus, the cost and uncertainty involved in registering any nanoscale pesticide active or inert ingredient as a new ingredient in accordance with the Policy Statement are likely to be a barrier to development and use of nanoscale active and inert ingredients in pesticide products. Moreover, it is not unreasonable to assume that initial registrants would incur considerably higher data costs than subsequent registrants due to the Agency’s likely overly precautionary approach to initial data requirements. The Agency has yet to establish data compensation mechanisms for inert ingredients. Therefore, CPDA recommends that EPA not implement the presumption policy at this time, and continue to make registration decisions for nanoscale materials on a case-by-case basis until it can develop a more informed policy.

⁷ Id. at 35392.

⁸ FIFRA §3(c)(7)(A).

⁹ Pesticide Registration Improvement Act (P.L. 108-199).

¹⁰ For instance, the current PRIA fee and time for a new food-use active ingredient is \$569,221 and 24 months compared with \$1,720 and 4 months for an “identical or substantially similar” product.

Conclusions

Nanotechnology is a new technology, especially for pesticide products, and CPDA urges EPA to gather information about its presence in a manner that minimizes any stigmatization of that technology and of pesticide products containing nanoscale materials. CPDA recommends that the Agency use a modified form of the data call-in provisions of FIFRA to obtain the information needed to make decisions about the continued registration of such products. Moreover, EPA should not implement the proposed “newness” presumption until the Agency promulgates a rule that sets forth specific data requirements and testing protocols, and establishes appropriate data compensation mechanisms.