regulations at 326 Indiana Administrative Code (IAC) 2–2–1 and 326 IAC 2–2–4.[13]

Indiana is currently a SIP-approved state for the PSD program, and has incorporated EPA's 2002 NSR reform revisions (67 FR 80186) for PSD into its SIP (72 FR 33395). In a letter provided to EPA on July 23, 2010, Indiana notified EPA of its interpretation that the state currently has the authority to regulate GHGs under its 326 IAC 2–2 PSD regulations. The current Indiana program (adopted prior to the promulgation of EPA's Tailoring Rule) applies to major stationary sources (having the potential to emit at least 100 tpy or 250 tpy or more of a regulated NSR pollutant, depending on the type of source) or modifications undertaken in areas designated attainment or unclassifiable with respect to the NAAQS.

Indiana has revised 326 IAC 2–2–1 to add GHG-related language to the definitions of ''regulated NSR pollutant'' and ''significant'' and to add a new definition for ''subject to regulation.'' We find these revisions to be consistent with the Tailoring Rule.

In 326 IAC 2–2–4, Indiana has added language that says the air quality analysis requirements of this section shall not apply with respect to GHGs. This does not affect the air quality-related requirements elsewhere in the PSD rule, including requirements for source information (326 IAC 2–2–10), additional impact analysis (326 IAC 2–2–7), or additional requirements for sources impacting Federal Class I areas (326 IAC 2–2–14). We find this revision to be approvable.

V. What action is EPA taking?

EPA is proposing to approve Indiana's December 3, 2010, SIP submittal, relating to PSD requirements for GHG-emitting sources in 326 IAC 2–2–1 and 326 IAC 2–2–4. Specifically, Indiana's December 3, 2010, proposed SIP revision establishes appropriate emissions thresholds for determining PSD applicability to new and modified GHG-emitting sources in accordance with EPA's Tailoring Rule. EPA has made the preliminary determination that this SIP submittal is approvable because it is in accordance with the CAA and EPA regulations regarding PSD permitting for GHGs.

[13] Attachment A to the December 3, 2010, submittal includes revisions to 326 IAC 2–7 to add GHG provisions to Indiana's Title V regulations. However, these regulations are not part of the SIP and IDEM has not included 326 IAC 2–7 in the December 3, 2010, request for SIP approval. IDEM intends to make a separate submittal requesting approval of the 326 IAC 2–7 regulatory revisions.

If EPA does approve Indiana's changes to its air quality regulations to incorporate the appropriate thresholds for GHG permitting applicability into Indiana's SIP, then 40 CFR 52.773(k), as included in EPA's SIP Narrowing Rule, which codifies EPA's limiting its approval of Indiana's PSD SIP to not cover the applicability of PSD to GHG-emitting sources below the Tailoring Rule thresholds, is no longer necessary. In this proposed action, EPA is also proposing to amend 40 CFR 52.773 to remove this unnecessary regulatory language.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, and Reporting and recordkeeping requirements.

Dated: June 9, 2011.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011–15102 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OPP–2010–0197; FRL–8877–9]

RIN 2070–ZA11

Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed policy statement.

SUMMARY: EPA seeks comment on several possible approaches for obtaining information about what nanoscale materials are present in registered pesticide products. Under one approach, EPA would use section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. If EPA adopts this approach, 40 CFR 152.50(f)(3) would also require the inclusion of such information with any application for registration of a pesticide product that contains a nanoscale material. Under an alternative approach, EPA would obtain such information using Data Call-In notices (DCIs) under FIFRA section 3(c)(2)(B). If EPA adopts this alternate approach, EPA would also

need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. It is EPA's view that FIFRA section 6(a)(2) is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach. EPA is also proposing a new approach for how EPA will determine on a case-by-case basis whether a nanoscale active or inert ingredient is a ''new'' active or inert ingredient for purposes of FIFRA and the Pesticide Registration Improvement Act (PRIA), even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

DATES: Comments must be received on or before July 18, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0197, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0197. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Jed Costanza, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–0204; fax number: (703) 308–8005; e-mail address: *costanza.jed@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is this document about?

This document describes several possible approaches for obtaining certain additional information on the composition of pesticide products. The notice focuses particularly on information about what nanoscale materials are present in registered pesticide products. In connection with this document, EPA describes ''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).

Under one approach, EPA would use section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. If EPA adopts this approach, 40 CFR 152.50(f)(3) would also require the inclusion of such information with any application for registration of a pesticide product that contains a nanoscale material.

Under an alternative approach, EPA would obtain such information using Data Call-In notices (DCIs) under FIFRA section 3(c)(2)(B). If EPA adopts this alternate approach, EPA would also need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. EPA is reviewing whether this could be done under existing regulations or whether EPA would need to amend existing regulations to clarify that the information is required with any application for registration.

It is EPA's view that FIFRA section 6(a)(2) is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach.

This document also proposes a new approach for how EPA will determine on a case-by-case basis whether a nanoscale active or inert ingredient is a ''new'' active or inert ingredient for purposes of FIFRA and the Pesticide Registration Improvement Act (PRIA), even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

After considering any public comments on the use of FIFRA section 6(a)(2) or DCIs under FIFRA section 3(c)(2)(B), as well as public comments submitted in response to other questions posed in this document, EPA plans to issue a subsequent document in the **Federal Register** announcing its approach to gather this information. EPA is also asking for specific input on the proposed approach for determining whether a nanoscale material is ''new'' under FIFRA and PRIA.

B. Does this action apply to me?

This action is directed to those persons who manufacture, distribute, sell, apply, or regulate pesticide products, including agricultural, commercial, and residential products (NAICS codes 32532 and 32561). This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not

listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Applicable Statutory and Regulatory Requirements

As a general matter, pesticides may not be sold or distributed in the United States unless they are registered with EPA. FIFRA section 3(a) (7 U.S.C. 136a(a)). In order to obtain a pesticide registration, an applicant must provide EPA with data (or cite existing data) demonstrating that the proposed registration complies with the requirement for registration. FIFRA section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)). FIFRA contains two provisions under which EPA may register pesticides: Section 3(c)(5) for ''unconditional'' registration and section 3(c)(7) for ''conditional'' registration (7 U.S.C. 136a(c)(5) and 7 U.S.C. 136a(c)(7)). Importantly, EPA must make statutorily required findings for each and every pesticide product for which registration is sought, regardless of whether another pesticide product with the same or similar composition and use patterns is already registered.

The standard for determining whether an application should be granted unconditionally is found in FIFRA section 3(c)(5). This section provides that, in order to grant a registration, EPA must find that a product's composition warrants the proposed claims for it; that the product's labeling and other material required to be submitted comply with FIFRA; that the product will perform its intended function without causing unreasonable adverse effects on the environment; and that, when used in accordance with widespread and commonly recognized practice, the product will not cause unreasonable adverse effects on the environment.

FIFRA defines ''unreasonable adverse effects on the environment'' as including ''any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.'' FIFRA section 2(bb) (7 U.S.C. 136(bb)). Thus, a critical aspect of determining whether or not a pesticide product should be granted a registration is an evaluation of whether the benefits associated with the use of a pesticide outweigh the risks associated with such use. The burden of demonstrating that a product meets the standards for registration rests at all times on the registrant or applicant for registration. See, *e.g., Industrial Union Dept.* v. *American Petroleum Institute,* 448 U.S. 607, 653 n. 61 (1980); *Environmental Defense Fund* v. *EPA,* 510 F.2d 1292, 1297, 1302 (DC Cir. 1975).

The Agency has promulgated regulations in 40 CFR parts 158 and 161 which identify the types of data EPA expects an applicant to provide to support an application for registration of a pesticide product. The Agency requires a wide variety of studies in order to evaluate whether a pesticide will cause unreasonable adverse effects on the environment. These required studies include both toxicity tests and data to characterize exposure to a pesticide, including extensive information on a product's composition, and its fate in the environment and within the human body. For certain pesticides EPA also requires data on product efficacy.

If an applicant cannot provide necessary data for EPA to make the determinations required to register a product unconditionally under FIFRA section 3(c)(5), EPA may still be able to register the product ''conditionally'' under FIFRA section 3(c)(7). FIFRA section 3(c)(7) authorizes EPA to register a pesticide product on the condition that the applicant provides additional data necessary to support a finding that the product meets the statutory standards in FIFRA section 3(c)(5). FIFRA section 3(c)(7) authorizes conditional registration in three circumstances. First, the Agency may conditionally register a product if EPA determines, among other things, that the product is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment. FIFRA section 3(c)(7)(A) (7 U.S.C. 136a(c)(7)(A)). Products approved under this authority are commonly called ''me-too registrations.'' Second, EPA may register a pesticide for an additional use, if the applicant provides data to evaluate the safety of the new use, and use of the product would not significantly increase the risk of unreasonable adverse effects on the environment compared to products already registered. FIFRA section 3(c)(7)(B) (7 U.S.C. 136a(c)(7)(B)). These product approvals are referred to as ''new use'' registrations. Finally, EPA may conditionally register a pesticide product that contains an active ingredient not present in any currently registered pesticide product, if the Administrator determines that:

1. The applicant has provided all data necessary to evaluate the safety of the pesticide, with the exception of any data which are lacking because the applicant has not had enough time to generate the data since learning of the requirement;

2. Use of the pesticide during the time period needed to develop the additional data will not cause unreasonable adverse effects on the environment; and

3. Use of the pesticide is in the public interest.

FIFRA section 3(c)(7)(C) (7 U.S.C. 136a(c)(7)(C)).

As with applications for unconditional registrations, applicants for conditional registration bear the burden at all times of demonstrating that the statutory standards are met.

The Agency's interest in data to evaluate the risks and benefits of a pesticide does not necessarily end once EPA has registered a pesticide product. Accordingly, other provisions of FIFRA allow the Agency to require pesticide registrants to develop and submit information the Agency believes it needs in order to maintain the registration of pesticide products.

A. DCI

Under FIFRA section 3(c)(2)(B), EPA may send a DCI notice to a registrant requiring the registrant to provide additional data or other information, which the registrant may need to generate or compile. Specifically, ''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 the DCI can serve as the basis for suspending the registration of the product, thereby making it unlawful for the registrant to sell or distribute the pesticide.

Generally, EPA's determination that additional data are needed is contemplated to occur for one of the following five reasons:

1. *The Re-registration Program.* Section 4 of FIFRA requires EPA to re-assess the health and safety data for all pesticide active ingredients registered before November 1, 1984, to determine whether these ''older'' pesticides meet the criteria for registration that would be expected of a pesticide being registered today for the first time. Section 4 of FIFRA directs EPA to use section 3(c)(2)(B) authority to obtain the required data.

2. *The Registration Review Program.* Section 3(g) of FIFRA contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. Section 3(g) instructs EPA to use the section 3(c)(2)(B) authority to obtain the required data.

3. *Anticipated Residue/Percent Crop Treated Information.* Under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or establish an exemption from the requirement to have a tolerance. Section 408(b)(2)(E) and (F) of FFDCA authorize the use of anticipated or actual residue (AR) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. FFDCA requires that if AR data are used, data must be reviewed 5 years after a tolerance is initially established.

4. *The Special Review Program.* EPA may conduct a Special Review if EPA believes that a pesticide poses risks of unreasonable adverse effects on human health or the environment. In the Special Review Program, EPA focuses on specific hazards or uses of a pesticide. Special Reviews are not intended to be comprehensive evaluations of the pesticide; instead the Special Review DCIs are to address the specific hazard or exposure concerns that are at issue.

5. *Enforcement and Unanticipated Circumstances.* The need for a DCI may arise from the discovery of deficiencies in previously submitted data, or from the discovery of specific attributes of the pesticide or its ingredients. This may lead the Agency to determine that additional information is necessary to reassess whether the pesticide will cause unreasonable adverse effects on the environment. This type of DCI is needed because the concern and therefore the need for data arise not from a mandated review program like Re-registration or Registration Review described above, but from unanticipated circumstances. Section 3(c)(2)(B) of FIFRA provides a means of obtaining any needed data.

B. FIFRA Section 6(a)(2)

FIFRA section 6(a)(2) provides that registrants must inform the Agency of relevant information relating to their products, even though it was not specifically requested by EPA. Specifically, FIFRA section 6(a)(2) requires that, ''[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.'' (7 U.S.C. 136d(a)(2)). For over 30 years, EPA has interpreted this provision expansively to include not only information relating directly to adverse effects caused by pesticides, but also to other types of information and studies that EPA would typically use in assessing whether a pesticide meets the statutory standard for registration (*i.e.,* the ''unreasonable adverse effects on the environment'' risk/benefit standard). See 43 FR 37611 (August 23, 1978).

In 1997, EPA promulgated a final rule at 40 CFR part 159, subpart D in the **Federal Register** issue of September 19, 1997 (62 FR 49370) (FRL–5739–1), setting forth EPA's interpretation and enforcement policy regarding FIFRA section 6(a)(2). The rule explains, among other things, what information EPA regards as ''additional'' and ''factual,'' as well as how quickly and to whom such information must be reported. The regulation specifies many kinds of information, from varied scientific disciplines, that EPA requires registrants to submit pursuant to FIFRA section 6(a)(2). The types of information reflect the variety of scientific data used by EPA in making the statutorily required determinations—whether pesticides cause unreasonable adverse effects on the environment. Thus, for example, the regulations generally require registrants to report studies indicating that a pesticide causes new or a higher incidence of toxic effects than previously identified (see 40 CFR 159.165) and to report incidents involving injury to humans, pets, or wildlife resulting from exposure to a pesticide (40 CFR 159.184). But, EPA uses other types of information that do not directly demonstrate adverse effects in its risk assessments, and new factual information of this kind is also reportable under the regulation. For example, registrants must report studies that identify new metabolites, degradates, impurities, or contaminants of pesticides (40 CFR 159.179); certain information on the detection of pesticide residues in water, food, and feed (40 CFR 159.178); and new studies of human exposure (40 CFR 159.170). In sum, EPA's regulation requires reporting of many types of information relevant to EPA's assessment of the safety of a pesticide product—in the words of section 6(a)(2) ''information regarding unreasonable adverse effects on the environment of the pesticide''—not merely information that directly concerns adverse effects.

In promulgating that regulation, however, EPA also recognized it was impossible to establish rules addressing every type of factual information that might become relevant in the future to judging whether a registered pesticide product continued to meet the FIFRA statutory standards. Accordingly, 40 CFR 159.195(a) provides:

The registrant shall submit to the Administrator information other than that described in §§ 159.165 through 159.188 if the registrant knows, or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

In addition, 40 CFR 159.195(c) provides that:

[t]he registrant shall submit * * * information other than that described in §§ 159.165 through 159.188 if the registrant has been informed by EPA that such additional information has the potential to raise questions about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

Thus, once the Agency has informed registrants that EPA considers a particular type of information relevant to determining whether a pesticide has the potential to cause unreasonable adverse effects on the environment, that type of information becomes reportable under FIFRA section 6(a)(2).

Finally, EPA promulgated a regulation at 40 CFR part 152 addressing the submission of applications for registration (53 FR 15952, May 4, 1988) (FRL–3266–9b). That rule specifies, among other things, certain types of information that an application for registration of a pesticide product must contain. The rule provides that the applicant must ''furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA section 6(a)(2), if the product were registered.'' 40 CFR 152.50(f)(3).

Registrants' compliance with FIFRA section 6(a)(2) and EPA's implementing regulations in 40 CFR parts 152 and 159 ensures that EPA has access to any additional factual information that could be important for determining whether a previous Agency decision to register a pesticide remains a correct one, and whether a registered pesticide can in fact be used without posing unreasonable adverse effects to human health and the environment. This provision of FIFRA recognizes that registrants may come into the possession of important new information that was not anticipated by the Agency or of information the importance of which was not previously known, and that in the absence of registrants submitting such information, EPA might well remain unaware of the information. Failures to report required information, or delays in reporting, are regarded by EPA as violations of FIFRA section 6(a)(2), which in turn makes them actionable under FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N) (7 U.S.C. 136j(a)(2)(B)(ii) and 7 U.S.C. 136j(a)(2)(N)).

III. EPA's Interest in Nanoscale Materials as Pesticide Ingredients

EPA believes that certain information concerning pesticide ingredients, which applicants and registrants have not routinely provided previously, is relevant to the Agency's statutory obligation to determine whether the registration of a pesticide may cause unreasonable adverse effects on the environment. For the reasons discussed below, EPA is particularly interested in nanoscale materials in this context. Accordingly, EPA is considering how to collect information about what nanoscale materials are in pesticide products and is therefore soliciting public comment on two possible approaches. It is important to first clarify how the term ''nanoscale material'' is being used for purposes of this document.

A. Nanoscale Material

To date, EPA has not developed formal definitions for the terms ''nanotechnology'' or ''nanoscale materials'' or any similar terms for regulatory purposes under any statute administered by the Agency. Broad definitions for the terms ''nanotechnology'' or ''nanoscale materials'' and discussions of nanotechnology generally reflect the same common elements, namely:

1. The material's particle size measures typically between approximately 1 and 100 nm in at least one dimension;

2. The material exhibits unique or novel properties compared to larger particles of the same material; and

3. Rather than occurring naturally, the material has been manufactured or engineered at the nanoscale to take advantage of these unique properties. See, for example, the definition from the National Nanotechnology Initiative at: *http://www.nano.gov/html/facts/whatIsNano.html.*

These elements do not readily work in a regulatory context because of the high degree of subjectivity involved with interpreting such phrases as ''unique or novel properties'' or ''manufactured or engineered to take advantage of these properties.'' Moreover, the contribution of these subjective elements to risk has not been established.

Instead, OPP will focus on more objective criteria in describing when information about a ''nanoscale material'' in a pesticide product may be relevant to determining whether the product has an unreasonable adverse environmental effect. Specifically, such information may be relevant in this context when the active or inert ingredient and any component parts thereof is intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers, regardless of the aggregation or agglomeration state of the final material.

In determining whether an ingredient meets this description, EPA may review particle size data and, among other things, the manufacturing process to determine whether it employs processes specifically to create or enhance the proportion of nanoscale materials in the product, as compared with other processes used to produce similar products. The Agency generally expects that these ingredients may comprise, but are not limited to, metal-based (*e.g.,* silver) and carbon-based (*e.g.,* carbon nanotubes) nanoscale materials. The Agency does not, however, intend this description to cover biological materials (*e.g.,* DNA, RNA, proteins) or materials in their natural state (*e.g.,* clays). To the extent that the application of this description to a particular product or ingredient is unclear, EPA would review information provided by a registrant or applicant concerning the composition of the pesticide product and to provide an Agency view on whether the product did (or did not) contain a nanoscale material for purposes of this policy.

B. Potential of Nanoscale Materials To Affect Human Health and the Environment

There is a growing body of scientific evidence showing that differences can exist between nanoscale material(s) and their non-nanoscale counterpart(s) (Ref. 1). Nanoscale materials may have different or enhanced properties—for example, electrical, chemical, magnetic, mechanical, thermal, or optical properties—or features, such as improved hardness or strength, that are highly desirable for applications in commercial, medical, military, and environmental sectors (Ref. 2). These properties are a direct consequence of small size, which results in a larger surface area per unit of volume and/or quantum effects that occur at the nanometer scale (*i.e.,* 1×0^{-9} meters). Small size itself is also a desirable property of nanoscale materials that is exploited for miniaturization of applications/processes and/or

stabilization or delivery of payloads to diverse environments or incorporation into diverse products.

Nanoscale materials have a range of potentially beneficial public and commercial applications, including medicine and public health, clean energy through more efficient solar panels, pollution reduction and environmental cleanup, and improved products such as stronger, lighter, and more durable or conductive materials. These benefits arise from the distinctive properties of nanoscale materials, in that they are potentially more interactive or durable than other chemicals as a result of their size and composition. EPA sees the emergence of nanoscale materials as offering potential benefits for society in many different fields, including pest control products. The use of nanoscale materials in pesticide products and treated articles may allow for more effective targeting of pests, use of smaller quantities of a pesticide, and minimizing the frequency of spray-applied surface disinfection. These could contribute to improved human and environmental safety and could lower pest control costs. For example, as a materials preservative, nanosilver should maintain its efficacy longer and require smaller quantities than other silver preservatives due to an expected gradual and controlled release of silver as opposed to the rapid release of for example, silver from a zeolite structure or the immediate dissolution of a silver salt. Therefore EPA seeks to encourage innovative work in developing nanoscale materials to realize these benefits.

However, a number of organizations have considered whether the small size of nanoscale materials or the unique or enhanced properties of nanoscale materials may, under specific conditions, pose new or increased hazards to humans and the environment. Government, academic, and private sector scientists in multiple countries are performing research into the human health effects of diverse nanoscale materials, resulting in a substantial and rapidly growing body of scientific evidence. Recently, governmental and expert peer review organizations have reviewed and summarized this evidence and offered views about the implications of this evidence for environmental and human health and safety.

For instance, in 2009, the National Institute of Occupational Safety and Health (NIOSH) issued a report, ''Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials,'' which summarized the available scientific information about nanoscale materials and identified the following potential health and safety properties:

- Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested.
- Based on results from human and animal studies, airborne nanoparticles can be inhaled and deposit in the respiratory tract; and based on animal studies, nanoparticles can enter the bloodstream, and translocate to other organs.
- Experimental studies in rats have shown that equivalent mass doses of insoluble incidental nanoparticles are more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors. Results from *in vitro* cell culture studies with similar materials are generally supportive of the biological responses observed in animals.
- Experimental studies in animals, cell cultures, and cell-free systems have shown that changes in the chemical composition, crystal structure, and size of particles can influence their oxidant generation properties and cytotoxicity.
- Studies in workers exposed to aerosols of some manufactured or incidental microscopic (fine) and nanoscale (ultrafine) particles have reported adverse lung effects including lung function decrements and obstructive and fibrotic lung diseases. The implications of these studies to engineered nanoparticles, which may have different particle properties, are uncertain.
- Some nanomaterials may initiate catalytic reactions depending on their composition and structure that would not otherwise be anticipated based on their chemical composition. (Ref. 3).

Earlier the same year, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), an independent scientific committee advising the European Commission's Health and Consumer Directorate, issued a report, ''Risk assessment of products of nanotechnologies.'' The SCENIHR report identified properties similar to those identified in the NIOSH report:

> Some specific hazards, discussed in the context of risk for human health, have been identified. These include the possibility of some nanoparticles to induce protein fibrillation, the possible pathological effects caused by specific types of carbon nanotubes, the induction of genotoxicity, and size effects in terms of biodistribution.

and:

> For some nanomaterials, toxic effects on environmental organisms have been demonstrated, as well as the potential to transfer across environmental species, indicating a potential for bioaccumulation in species at the end of that part of the food chain.

(Ref. 4).

In another recent survey of scientific research on nanoscale materials, the authors reported:

> Many studies have examined the pro-inflammatory effects of manufactured NPs [nanoparticles], on the basis that their ability to cause inflammation is a major predictor of potential hazard in such particles. The first important finding was that NPs have a more pronounced effect on inflammation, cell damage and cell stimulation than an equal mass of particles of the same material of greater size [* * *]. This appears to hold true for materials as varied as carbon black, titanium dioxide, various metals and polystyrene [* * *]. Surface area is the metric driving the pro-inflammatory effects and this is evident both *in vitro* [* * *] and *in vivo* [* * *], particles of various sizes producing inflammatory effects that are directly related to the surface area dose.

(Ref. 5 [reference numbers in the original were omitted]).

Other reports in the scientific literature have indicated that some nanoscale materials may cross the placental barrier (Ref. 6) or translocate to diverse organs following oral exposure (Ref. 7). Once in these diverse sites and organs, the large surface area of nanoscale materials may facilitate increased reactivity and/or an inflammatory response, resulting in toxic effects.

Two recent literature surveys describe a broad range of effects in non-mammalian species following exposure to nanoscale materials (Refs. 8 and 9). These include, for example, increased ventilation rates, mucus production, and pathologies, and related alteration of enzyme activities and indicators of oxidative stress in rainbow trout, *Oncorhyncus mykiss* (Refs. 10 and 11), and ingestion and accumulation of nanoscale material in the digestive tract, as well as mortality, increased heart rates, and reduced fecundity in *Daphnia magna* (Refs. 12, 13, and 14). Translocation of nano-scale materials from gill and gut surface to blood and other organs in exposed Medaka, *Oryzius latipes,* has also been reported (Ref. 15) and carbon nanotubes, although unable to cross the egg surface, have been shown to delay hatching in zebrafish, *Danio rerio* (Ref. 16). A recent review of lethal effects and concentrations determined for a wide variety of species showed that some nanoscale materials, including nano-titanium, nano-zinc oxide, nano-silver, nano-copper oxide, C60, and single- and multi-walled carbon nanotubes, would be classified as harmful to extremely toxic to non-mammalian species (Ref. 17).

While the reports and articles cited previously have focused primarily on

differences between nanoscale material and conventionally sized material of the same substances, EPA has also consulted with the FIFRA Scientific Advisory Panel (SAP) on the extent to which different types of nanoscale materials may display different properties. (The SAP is a Federal advisory committee consisting of external, independent, expert, scientific peer reviewers who provide advice to EPA on scientific issues involved in the regulation of pesticides.) In response to EPA questions on how size and other properties of nanoscale materials potentially affect risk and how to assess such risks, the SAP said: ''Existing data clearly indicate that many properties of particles change with size, including rate of release of ionic forms of metal, reactivity or catalytic efficiency, Plasmon resonance, and quantum effects. * * * The effect of particle size on biological responses to particle exposure is less well defined.'' (Ref. 18). The SAP also noted that ''[o]ther physicochemical properties, such as shape, charge and surface coating, are also likely to impact biological response and environmental fate [of nanoscale materials]. * * * The lack of a clear understanding of how particle size and other physical properties affect hazard profiles led most Panel members to be unsupportive of bridging among silver-based materials with different properties.'' (Ref. 18).

It is important to emphasize that, while the conclusions described previously apply to the specific material(s) and or context in which the study was conducted, any individual type of nanoscale material may not display all or even any of the characteristics observed and reported for other nanoscale materials. In other words, some nanoscale materials may have properties which, for purposes of assessing the risk of a pesticide, are essentially identical to larger sized materials (or particles) of the same substance. Furthermore, nanoscale materials may also have properties that make them less risky, or more beneficial in some other way, than larger sized materials (or particles) of the same substance. So, it appears increasingly likely that there are few, if any, universal ''nanoscale'' effects, and the distinctive effects seen at nanoscale are specific to the properties of each material type under specific exposure scenarios. Thus, EPA does not regard the fact that an ingredient meets our description of a nanoscale material as evidence that a pesticide containing the ingredient would cause unreasonable adverse effects on the environment and thus would no longer meet the statutory standards for registration. Rather, the presence of a nanoscale material in a pesticide is grounds for EPA to consider the possible need for data to characterize the potential of the ingredient to pose risks. However, the registration status of a product would not change merely as a result of providing information to EPA about the presence of a previously-unreported nanoscale material. If, based on a science based assessment of the risks of the specific pesticide ingredients involved, EPA were to determine that the pesticide no longer met the criteria for registration, or that some change was needed in the conditions of use, EPA would conduct a separate action to notify the manufacturer of that determination, consistent with current FIFRA regulations.

Finally, scientifically speaking, there currently is no bright line with respect to a size below (or above) which nanoscale materials do (or do not) exhibit properties that might be of interest in assessing whether a pesticide product has the potential to cause unreasonable adverse effects on the environment. Therefore, the precise size range in nanometers addressed by the policies proposed in this document might be revised in the future as new information becomes available.

C. Nanoscale Materials and Pesticides

The Agency has information indicating that the use of nanotechnology has started to expand into pesticide products, as it already has in many other fields. For instance, a number of companies have contacted EPA expressing an interest in obtaining registrations for pesticide products containing ingredients identified as nanosilver or nanosilver composite structures (jointly referred to as ''nanosilver''), and several companies have submitted applications to register pesticides containing nanosilver. In addition, EPA now has information suggesting that there are other pesticide products currently registered and in the marketplace that contain nanosilver as an active ingredient.

In order for EPA to fulfill its responsibilities to regulate pesticides under FIFRA, it needs to determine whether pesticidal products meet the statutory standards for registration. As summarized previously, EPA believes that what intentionally produced nanoscale materials are in a pesticide product, whether as an active or inert ingredient, is relevant to that determination. Accordingly, EPA is considering how to collect information not only about what nanoscale materials are in pesticide products, but also other information that may be relevant to the assessment of the potential of such pesticide products to cause unreasonable adverse effects on the environment. Such information may be important for EPA to determine whether EPA should continue the registration of a product, or amend, as appropriate, the terms and conditions of registration of a product. EPA is therefore soliciting public comment on two possible approaches for obtaining this information, as discussed in this document.

IV. Information Relevant To Assessing the Presence of Nanoscale Materials in a Pesticide

In light of the foregoing and in consideration of the potential for nanoscale material to cause different effects and to behave differently in the environment and within organisms from larger particles of the same substance, as well as from nanoscale materials with different characteristics (see Unit III.B.), EPA believes that any of the following types of information are relevant to assessing the potential of a pesticide to cause unreasonable adverse effects on the environment:

- Any information concerning what nanoscale materials are present in pesticides, whether as an active ingredient or as an inert ingredient;
- For any pesticide product that contains nanoscale material, whether active or inert, any existing information that characterizes the size and size distribution of the nanoscale material as measured in nanometers;
- For any pesticide product that contains nanoscale materials, whether active or inert, any existing information that describes the manufacturing process used to produce the nanoscale material in whatever size range it is produced;
- For any pesticide product that contains nanoscale materials, whether active or inert, and that also is or will be used for an end-use formulation that contain(s) a composite (*e.g.,* the active ingredient is a matrix complex comprised of the nanoscale material(s) in combination with a carrier, such as silica or sulfur), any existing information that characterizes the size and size distribution of the composite; and
- For any pesticide product that contains nanoscale materials, whether active or inert, any existing information that shows adverse effects at any level of exposure to the nanoscale material on humans or nontarget species, and/or that shows the levels or nature (*e.g.* routes, frequency, or life stage) of

potential human and environmental exposure.

Importantly, the foregoing is not intended to be an exclusive list. To the extent that a registrant has a pesticide product that contains a nanoscale material, and in addition has any other existing information not captured in the previous list that pertains to, concerns, or otherwise relates to the nanoscale material and has the potential to raise questions about the continued registration of a product or the appropriate terms and conditions of a product registration, EPA is also considering whether this too should be submitted to the Agency.

EPA will review information submitted concerning what nanoscale materials are present, including any existing information not previously provided to the Agency on size and size distribution, manufacturing process, and adverse effects. EPA will use this and product use information to determine if it raises any issues, not previously considered, regarding the product's potential to cause unreasonable adverse effects on the environment. In some cases, EPA may determine that additional information is needed to assess such potential; in this case, additional data may be required including data on physical and chemical properties, rate of nanoscale material release, and acute, subchronic, and chronic toxicity to human and ecological receptors.

V. Reporting the Presence of Nanoscale Materials in Pesticide Products

As discussed in Units III. and IV. of this document, EPA believes that information about what nanoscale materials are in pesticide products is important to its assessment of whether pesticides meet the statutory standard for registration. EPA may require such information under either FIFRA section 6(a)(2) or section 3(c)(2)(B). The Agency believes that announcing the applicability of FIFRA section 6(a)(2) to this type of information would be the most efficient and expedient administrative approach to obtaining existing information about nanoscale materials in pesticides, in which case any registrants with this type of information would be required to report it to EPA. The Agency is considering, however, an alternative approach under which it would issue DCIs under FIFRA section 3(c)(2)(B) to obtain this information, in which case registrants that received the DCI would be required to respond. This unit of the document discusses the two possible approaches and related procedures for obtaining information concerning nanoscale materials in pesticides.

A. FIFRA Section 6(a)(2)

As mentioned previously, FIFRA section 6(a)(2) and implementing regulations in 40 CFR part 159 require pesticide registrants to report certain information if that information:

1. Is additional;
2. Is factual; and
3. Regards unreasonable adverse effects on the environment of the pesticide.

Per 40 CFR 159.195, this includes information that, if correct, a registrant knows, or reasonably should know, would be regarded by EPA, either alone or in conjunction with other information about the pesticide, as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

Announcing the applicability of FIFRA section 6(a)(2) to information about nanoscale materials in pesticides would not mean that EPA is expanding its interpretation of FIFRA section 6(a)(2) or changing its regulations. Rather, consistent with EPA's section 6(a)(2) regulations, EPA would be merely identifying a set of information that adds to the subset of reportable section 6(a)(2) data explicitly identified at present under the section 6(a)(2) regulations.

Further, the Agency notes that the identification of information as reportable under FIFRA section 6(a)(2) does not mean that any particular pesticide or group of pesticides, to which such information pertains, poses a risk. Rather, the requirement merely indicates that EPA has determined that a particular type of information is relevant to, and may improve the Agency's ability to assess, whether the pesticide would cause an unreasonable adverse environmental effect.

As part of this approach, EPA would also require that any such information be reported in connection with any application to register a pesticide product containing any nanoscale material (40 CFR 152.50(f)(3)). As with the reporting obligation under FIFRA section 6(a)(2), EPA would consider the failure to provide these types of information with an application for a product containing nanoscale material to be a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N).

Agency regulations implementing FIFRA section 6(a)(2) provide that a registrant must submit information to EPA that is reportable under section 6(a)(2) no later than the 30th calendar day after the registrant first possesses or becomes aware of the information (40 CFR 159.155). In addition, a registrant is required to submit to EPA any section 6(a)(2) information not explicitly covered under the section 6(a)(2) regulations if EPA has informed the registrant that such additional information has the potential to raise questions about the continued registration of a product or the appropriate terms and conditions of registration of a product (40 CFR 159.195).

After learning that EPA was considering relying on FIFRA 6(a)(2) to require reporting, some stakeholders raised questions about the use of FIFRA section 6(a)(2) to obtain this information. Even though, as stated above, EPA is not making a judgment that the presence of any particular nanoscale material poses a risk, it has been argued that use of the ''adverse effects'' reporting authority in FIFRA section 6(a)(2) could create a ''stigma'' for the nanotechnology industry.

EPA does not believe that using FIFRA section 6(a)(2) to gather information on the presence of nanoscale materials in pesticide products would create a stigma for the nanotechnology industry. EPA's longstanding interpretation of section 6(a)(2) is that it is not limited to requiring reporting only of actual ''adverse effects'' of pesticides, and its use does not imply that ''adverse effects'' actually have occurred, or even could occur, in connection with the pesticide or pesticide ingredient on which the information is being obtained. FIFRA section 6(a)(2) requires reporting of ''additional factual information regarding unreasonable adverse effects on the environment,'' where ''unreasonable adverse effects on the environment'' is specifically defined as a risk/benefit standard. EPA's implementing regulations require reporting of a wide range of data, which—like information on nanoscale materials—are relevant to EPA's risk/benefit evaluations, but which do not indicate the pesticide causes any adverse effects. Any suggestion that this information gathering proposal implied an EPA position on the adverse effects of pesticides containing nanoscale materials would be a misinterpretation of EPA's intent.

It is further EPA's position that merely filing an additional report under FIFRA section 6(a)(2) does not stigmatize pesticides and would not stigmatize any nanomaterials in pesticides, since filing such reports is quite common. On average, EPA receives 200 studies and 56,000 incident reports per year under this authority. In

fact, over the last 10 years, pesticide registrants have filed section 6(a)(2) reports on more than two-thirds of all pesticide active ingredients.

Use of FIFRA section 6(a)(2) also would have only a minimal overall administrative burden for both EPA and industry. Under section 6(a)(2), only registrants who know that their products contain nanoscale materials would be required to report to EPA. Further, they would be required to report only the information they know about. Section 6(a)(2) does not require a registrant to generate new data or to seek out additional information. Further, registrants and applicants whose products do not contain nanoscale materials (or who do not know that their products contain nanoscale materials) would have no reporting obligation under FIFRA section 6(a)(2). Under this approach, EPA would be required to keep track of each response received under 6(a)(2), but would not otherwise need to prepare or track individual requests for the information.

B. DCIs Under FIFRA Section 3(c)(2)(B)

As an alternative to relying on FIFRA section 6(a)(2) to obtain information concerning nanoscale materials in pesticides, EPA is also considering issuing DCIs under FIFRA section 3(c)(2)(B). The Agency has authority under FIFRA section 3(c)(2)(B) to issue a DCI notice to a pesticide registrant directing them to provide data ''required to maintain in effect an existing registration of a pesticide * * *'' The DCI notice is addressed to an individual registrant, specifically identifies the information or data that the registrant must provide, prescribes an initial response deadline of 90 days, and, if data are to be generated, it may prescribe a timeframe for generating and providing that data. Under FIFRA, EPA can suspend the registration of a pesticide if the registrant fails to respond to a DCI.

As part of this alternate approach, EPA would also need to require the inclusion of this information with any application for registration of a pesticide product that contains a nanoscale material. EPA is reviewing whether this could be done under existing regulations or whether EPA would need to amend existing regulations to clarify that this information is required with any application for registration. As with the reporting obligation under FIFRA section 6(a)(2), EPA would consider the failure to provide these types of information with an application for a product containing nanoscale material to be a violation of FIFRA sections 12(a)(2)(B)(ii) and 12(a)(2)(N).

Since EPA's goal is to identify what nanoscale materials are contained in products (and the products that contain them) and to gather existing information not previously provided to assess their safety, the DCI would need to require the kinds of information specified in Unit IV. of this document. Because such a request is not consistent with the Re-registration or Registration Review programs, the Agency would use the Enforcement and Unanticipated Circumstances category available in the currently approved Information Collection Request (73 FR 55072, September 24, 2008) (FRL–8719–3).

Unless a registrant has already disclosed the presence of nanoscale material in all of its products, there currently is no way to identify with certainty what nanoscale materials are in products (and the products that contain them). Therefore, in order to identify what nanoscale materials are in products, EPA could initially send an individual Enforcement and Unanticipated Circumstances DCI order to each of the 1,716 currently registered pesticide producers. Under this approach each of these pesticide registrants would then be required to respond within 90 days by either providing the requested information about the nanoscale materials in their product(s) or certifying that their product(s) do not contain nanoscale materials. In addition to keeping track of each response like under FIFRA section 6(a)(2), the approach under FIFRA section 3(c)(2)(B) could require EPA to also prepare and track the issuance of individual DCIs for each pesticide registrant, as well as determine and take any necessary enforcement actions for non-responders. EPA notes that only pesticide registrants receive DCIs; EPA would need to employ additional administrative procedures to ensure that applicants also provided such information.

A variation on this approach would be for EPA to craft a DCI that would be more targeted and place less burden on industry and the Agency, possibly by not requiring a response from recipients of the DCI who do not have (or who do not know that they have) nanoscale material in their registered pesticide products. The Agency has not used such an approach with any DCI in the past; however, and a number of issues, including enforcement, would need to be addressed if it were to seek to do so here. EPA could also focus its initial data gathering on certain classes of pesticides that might be most likely to contain a nanoscale material that EPA would be interested in knowing about. EPA is interested in receiving comments on these variations.

It is useful to note that while FIFRA section 6(a)(2) can be used to obtain existing information, the DCI approach under FIFRA section 3(c)(2)(B) allows the Agency to request that data be generated. If EPA uses FIFRA section 6(a)(2) authority and the Agency learns, for instance, the identity of a nanoscale material present in a product, and subsequently determines that sufficient data are not available to support the continued registration of the pesticide, EPA could then use the DCI approach under FIFRA section 3(c)(2)(B) to gather such information. EPA must use the DCI approach if EPA intends to require a registrant to provide information which the registrant does not already possess.

It is anticipated that some registrants will request that EPA review information to determine if their product contains nanoscale materials. To the extent that the description of nanoscale material to a particular product or ingredient is unclear, EPA will review information concerning the composition and manufacturing process of the pesticide product and, based on that information, the Agency will determine whether the product does (or does not) contain nanoscale material.

It has been suggested that the use of a 3(c)(2)(B) approach would result in submission of information that only reflected the composition of registrants' products at the time of their responses, but that EPA would need periodically to issue DCIs to ensure that registrants did not alter the composition of the products to add nanoscale materials after submitting their responses. EPA is interested in receiving comments on options whereby it can ensure registrants report what nanoscale materials are in products, regardless of when they are added to the pesticide.

Under either the 6(a)(2) or the 3(c)(2)(B) approach, DCIs targeted to individual pesticide products that contain specific nanoscale materials would likely be used in the future to collect more specific information or data about particular products. EPA would consider doing so on a case-by-case basis and would tailor any request for information accordingly.

C. Amending the Pesticide Data Requirement Regulations

Some stakeholders have suggested, as an alternative to relying on either FIFRA section 6(a)(2) or 3(c)(2)(B) DCIs to obtain information concerning nanoscale materials in pesticides, that EPA instead promulgate a regulation amending the data requirements in 40

CFR parts 158 and 161. The Agency could amend the data requirements to include disclosure of what nanoscale materials are present as part of the pesticide registration process. However, completing this action would not provide information on currently registered pesticide products.

The Agency sees such proposed rulemaking with a broader scope in that it would address not only the basic information such as identifying what nanoscale materials are in products, but also many other types of data required for making safety evaluations. The Agency is currently making data need decisions on a case-by-case basis, and EPA is trying to tailor data requirements to the particular characteristics of each product. The Agency does not yet have the knowledge base typically gained through the registration process to support the development of specific data requirements that would be imposed broadly for the registration of pesticides containing nanoscale materials across all the application and use scenarios, as required for such a rulemaking.

Although it could take considerable time to finalize and implement a rule establishing standard data requirements for pesticides containing nanoscale materials, and the Agency thus believes that this approach by itself would not generate information on nanoscale ingredients in pesticides in a timely manner, EPA also seeks comment on this approach.

VI. Proposed Policy Regarding Classification of Applications Under FIFRA and PRIA for Products Containing Nanoscale Active and Inert Ingredients

As discussed in more detail earlier in this document, under FIFRA, all pesticides must meet stringent statutory and regulatory standards before they are registered by the Agency and allowed to be marketed and sold. Pesticides containing nanoscale materials, whether as active or inert ingredients, must meet the same safety standards as other pesticides. Because of the large and increasing body of data described in Unit III.B. of this document demonstrating that size can alter the manner in which materials behave and, in turn, the potential risk to human health and the environment associated with such materials, EPA proposes to apply an initial presumption that active and inert ingredients, which are the nanoscale versions of non-nanoscale active and inert ingredients already present in registered pesticide products, are potentially different from those conventionally sized counterparts. Because the size, shape, and other characteristics of nanoscale ingredients are likely to vary widely, EPA also proposes to apply an initial presumption that nanoscale active and inert ingredients are potentially different even from other, already-registered nanoscale versions of the same ingredients. As explained later in this document, however, applicants can overcome this presumption on a case-by-case basis.

Historically, EPA has evaluated an application for registration of a pesticide product that claims to have the same composition and uses as a currently registered pesticide—a so-called ''me-too application''—under either the ''conditional'' registration or ''unconditional'' registration authorities in FIFRA section 3(c)(7) and section 3(c)(5), respectively. In making the statutory determinations under section 3(c)(7)(A)—whether the applicant's product is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment—EPA has focused on whether the use patterns of the products are identical or similar and whether the ingredients present in the products have the same chemical structure and are present in about the same percentages. Until recently, EPA generally has not focused on the size of an ingredient as an attribute relevant to making the determinations under section 3(c)(7)(A).

As noted previously, however, once the size of an ingredient is reduced below approximately 100 nm, a substance can exhibit different properties, and therefore it may also have different potential environmental health and safety properties. Accordingly, for a product containing an ingredient that is a nanoscale version of a conventionally sized active or inert ingredient contained in an already-registered product, EPA may require additional data in order to determine that the nanoscale material differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment, and/or require different terms and conditions for the registration. EPA is thus proposing that it not make the requisite findings absent specific information on the nanoscale material included in a pesticide product when the application relies on a comparison to a currently registered pesticide product containing either a non-nanoscale version of the same ingredient or another nanoscale version of the ingredient that has different characteristics. Under this approach, the Agency would follow the same thinking in making the statutorily required determinations under FIFRA section 3(c)(7)(B) and 3(c)(7)(C), as well as FIFRA section 3(c)(5).

For purposes of registration under FIFRA section 3(c)(5) or 3(c)(7), therefore, EPA would initially classify any application for registration of a pesticide product containing an active or inert ingredient that is a nanoscale material as an application for a ''new'' active or inert ingredient, even when another registered pesticide product contains a non-nanoscale form of the ingredient or a nanoscale form of the ingredient with different size dimensions or other properties. This initial presumption, however, could be rebutted on a case-by-case basis through the submission of, among other possibilities, bridging data or other information demonstrating to EPA's satisfaction that the nanoscale material's properties, which are relevant to assessing the potential risks to human health and the environment, are substantially similar to the properties of the already-registered non-nanoscale or already-registered nanoscale form of the material, or that the nanoscale material differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment.

If an applicant could make this showing to EPA's satisfaction, then the application would be processed as a ''me-too'' application within the timeframes prescribed for such applications. However, if an applicant could not make this showing to EPA's satisfaction, then EPA would process such products as new active ingredients or new inert ingredients and would complete its review within the timeframes prescribed for such applications. In those circumstances, the Agency would likely require the applicant to provide the types of data typically required for an assessment of the potential hazards and exposure to a new active or inert ingredient. Under this proposed policy, it would also follow that if a registrant wished to change the composition of its product to include a nanoscale version of a

material that EPA had previously approved in non-nanoscale form, the registrant would need to notify EPA and obtain EPA approval before making such a change in the composition of its product. However, as noted earlier, the registration status of a product would not change merely as a result of providing information to EPA about the presence of a previously-unreported nanoscale material. If EPA made an affirmative finding that a change in status or conditions of use was necessary, EPA would notify the registrant in accordance with applicable regulations and procedures.

VII. Does this document contain binding requirements?

This document seeks comments on how the Agency could use FIFRA section 6(a)(2) or FIFRA section 3(c)(2)(B) to gain information on what nanoscale materials are in pesticides. Given that the Agency is seeking comment before determining its approach to obtaining information on what nanoscale materials are in pesticides, there are no binding requirements in this document.

Once this document is finalized, the Agency's policy for determining whether a nanoscale material is a new active or inert ingredient for purposes of both FIFRA and PRIA would be intended only as guidance to EPA personnel and decision-makers and to pesticide applicants. While the requirements in the statute and Agency regulations are binding on EPA and the applicants, the proposed policy described in this document would not be binding on EPA personnel, pesticide applicants, or the public. Accordingly, EPA may depart from the policy proposed herein if and when circumstances warrant. Likewise, pesticide applicants may assert that the proposed policy is not applicable to a specific pesticide or situation in which EPA may be expected to apply it.

VIII. Questions for Comment

The Agency is seeking public comment on several questions, including whether it should use the FIFRA section 6(a)(2) reporting obligation to obtain information on what nanoscale materials are in pesticide products or use FIFRA section 3(c)(2)(B) as described in this document to obtain such information.

With respect to the scope of reportable information, EPA specifically invites comments on the following issues:

1. In view of the Agency's goal of identifying what nanoscale materials are in products so that EPA can determine whether it needs additional data to evaluate the products' safety under FIFRA, should EPA change the description of a ''nanoscale material''? For example, should the size range remain ''between approximately 1 and 100 nm in one dimension''? Are there other characteristics that EPA should consider, *e.g.,* morphology, including shape and crystal structure; surface chemistry and reactivity; specific surface area, charge; solubility; conductive, magnetic, and optical properties?

2. Should the reporting requirement apply only to nanoscale material that is ''intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers,'' or should it also apply to naturally occurring materials? Why?

3. Is the meaning of ''intentionally produced'' sufficiently clear? If not, in what circumstances would the term be unclear and how might it be clarified? Would offering a consultation procedure—by which a registrant or applicant describes to EPA the production process that results in the presence of a material in the nanoscale size range, and EPA responds with a determination regarding whether reporting is required—be an acceptable approach to providing clarity?

4. Should the reporting requirement apply to ingredients in pesticides that contain any amount of a nanoscale material, or should the requirement apply only if an ingredient contains more than a specified percentage (*e.g.,* 10%) of nanoscale material? If the latter, what should the specified percentage be and why?

5. How should the reporting requirement apply to a pesticide manufacturer who purchases ingredients that may contain nanoscale material?

6. Are there ways in which the description of ''nanoscale materials'' can be refined and clarified, including ways in which agglomeration and aggregation could be considered as well as suggestions for ways in which more subjective criteria, such as ''unique or novel properties'' can be incorporated into the screening criteria?

7. Is EPA's description of ''nanoscale material'' inconsistent with other definitions of nanoscale material or similar terms? If so, please comment on whether such differences create any regulatory issues. In particular, does the focus on ''intentionally produced'' materials create any such inconsistency with other definitions of nanoscale materials or similar terms?

8. If a pesticide is identified as containing a particular nanoscale material, what would be the most useful next steps to inform EPA's understanding of potential risks associated with the pesticide? Are there tests that could provide useful information toward an understanding of risk that would be common to all nanoscale materials, or should the data requirements necessarily be compound- and situation-specific? How should bioavailability be considered in determining testing requirements (*e.g.,* are nano-particles respirable or bound to other components)?

With respect to the proposed approaches, EPA is seeking comment on how to implement them to ensure efficient, effective, and timely review of applications. EPA specifically invites comments on the following issues:

1. Is there a way to determine, in advance of receiving an application for registration of a product containing a nanoscale material, whether a particular kind of nanoscale material has properties that, for purposes of risk assessment, are essentially the same as larger sized materials of the same substance? If so, how would such determinations be made and on what would they be based?

2. What kinds of information should EPA accept as demonstrating that a pesticide product containing a nanoscale ingredient is identical or substantially similar to a currently registered pesticide or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment?

3. Can you suggest any alternative(s) to the proposed approaches that would be equally or even more effective in addressing the status of nanoscale materials as new active or inert ingredients for purposes of both FIFRA and PRIA, keeping in mind the data showing that size, especially when reduced below approximately 100 nm, may alter the manner in which materials behave and, in turn, the potential risk to human health and the environment associated with such materials?

With respect to the potential alternative ways of obtaining the needed information on what nanoscale materials are in pesticide products, EPA specifically invites comments on the following issues:

1. Has EPA appropriately characterized in this document the current scientific understanding of the potential risks of nanoscale materials? If not, please comment on how to

characterize the potential risks of nanoscale materials. How would the perception of the risks of nanoscale materials differ depending on the approach used by EPA to require needed data on nanoscale materials in pesticides? How could EPA lessen the possibility that issuance of a final requirement to report what nanoscale materials are in pesticides will result in a public misunderstanding of the potential risks of nanotechnology more generally?

2. Do commenters believe that identification of the nanoscale materials in pesticide products is relevant to EPA's statutory determination regarding the potential for unreasonable adverse effects on the environment? Please provide the scientific or legal basis for your view.

3. Has EPA characterized the alternative approaches with respect to which they would: (a) result in a misunderstanding of the potential risks posed by nanoscale materials; (b) result in the timely submission of needed information; and (c) impose burdens on pesticide companies, those whose products do, and do not, contain nanoscale materials? If not, please comment on those issues.

4. If EPA uses FIFRA section 6(a)(2) to obtain the needed information on nanoscale materials in pesticides, how could the Agency ensure that its action is not mischaracterized or misunderstood as a determination that the mere fact that a pesticide contains nanoscale materials causes unreasonable adverse environmental effects?

5. If EPA were to use DCIs to obtain the needed information on nanoscale materials in pesticides, how could EPA reduce both the burdens on registrants and on EPA, as well as the time required to complete such a process? For example, is it possible to reduce the burdens on registrants by targeting only certain types of products? If so, how would EPA determine which products should receive DCIs?

6. What are the advantages and disadvantages of requesting information on nanoscale materials specifically versus requesting information on size distribution generally? (Note that either type of information could be collected under either the 6(a)(2) or the 3(c)(2)(B) approach, except that 6(a)(2) cannot be used to require the production of new information that does not already exist, while a collection under 3(c)(2)(B) must be directed to an individual registrant and requires a response.) Is identifying what nanoscale materials are in products a useful first step, or should EPA move towards immediate collection of more specific information, such as particle size distribution, on products that might contain nanoscale materials? Are there other physical and/or chemical properties that might be equally or more important for assessing the potential of a pesticide to cause unreasonable adverse effects on the environment (*e.g.,* morphology, including shape and crystal structure; surface chemistry and reactivity; specific surface area, charge; solubility; conductive, magnetic, and optical properties)? Should information on these properties be separately requested? What would be the value and burden of obtaining such information?

1. If EPA were to use rulemaking to establish data requirements for pesticides containing nanoscale materials, what types of information should EPA use to determine appropriate data requirements? What types of studies should EPA require to evaluate a nanoscale material?

2. When choosing an approach for obtaining needed data, how should EPA weigh considerations relating to the need to update its safety evaluations of currently marketed pesticides in a timely manner, the goal of ensuring marketplace equity, and the interest in minimizing the burdens on regulated entities?

IX. References

As indicated under **ADDRESSES**, a docket has been established for this document under docket ID number EPA–HQ–OPP–2010–0197. The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

1. Oberdörster, G. *et al.* 2005. Nanotoxicology: an emerging discipline evolving from studies of ultrafine particles. Environmental Health Perspectives. (113):823–839.
2. National Nanotechnology Initiative. 2011. Strategic Plan. *http://www.nano.gov/nnistrategicplan211.pdf.*
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14. Roberts *et al.* 2007. *In vivo* biomodification of lipidcoated carbon nanotubes by *Daphnia magna.* Environ. Sci. Technol. 41:3025–3029
15. Kashiwada *et al.* 2006. Distribution of nanoparticles in the see-through Medaka (*Oryzias latipes*). Environ. Health Perspect. 114:1697–1702.
16. Cheng *et al.* 2007. Effect of carbon nanotubes on developing zebrafish (*Danio rerio*) embryos. Environ. Toxicol. Chem. 26:708–716.
17. Kahru and Dubourguier. 2010. Review: From ecotoxicology to nanoecotoxicology. Toxicology 269:105–119.
18. FIFRA Science Advisory Panel (SAP). 2010. ''Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide

Products.'' Report from the FIFRA Scientific Advisory Panel Meeting of November 2009. *http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf.*

X. Applicable Statutory and Executive Order Reviews

EPA submitted this document to the Office of Management and Budget (OMB) for review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of the Executive Order.

The information collection requirements associated with reporting under FIFRA section 6(a)(2) as prescribed in 40 CFR part 159, subpart D are approved under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The approval is identified under OMB Control No. 2070–0039 and EPA ICR No. 1204. The information collection requirements associated with DCIs is approved under OMB Control No. 2070–0174 and identified by EPA ICR No. 2288. If EPA were to finalize a policy that required additional reporting of information not currently collected, or that substantively changed the burden for such reporting (for example if it resulted in a larger number of such reports than covered in current burden estimates), EPA would submit a request for revised PRA approval to OMB.

The various other statutory and Executive Order review requirements that apply to a regulatory action do not apply to this action because this document is not a regulatory action and does not otherwise impose new requirements. As indicated previously, this document requests comment on several approaches for applying existing requirements in order to obtain information on nanoscale materials in pesticide products and presents the Agency's proposed policy for determining whether a nanoscale material is a new active or inert ingredient for purposes of both FIFRA and PRIA.

List of Subjects

Environmental protection, Administrative practice and procedure, Nanotechnology, Pesticides and pests.

Dated: June 8, 2011.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2011–14943 Filed 6–16–11; 8:45 am]

BILLING CODE 6560–50–P