August 17, 2011

Mr. Jed Costanza
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

SUBMITTED TO DOCKET AND BY EMAIL TO COSTANZA.JED@EPA.GOV

Re: Pesticide Products Containing Nanomaterials (EPA–HQ–OPP–2010–0197)

Dear Mr. Costanza:

The American Chemistry Council's Nanotechnology Panel and Biocides Panel appreciate the opportunity to submit comments on EPA's proposed policy statement concerning the collection of information about the presence of nanomaterials in pesticide products.[1] The Panels' comments are attached. In addition to responses to EPA's specific questions, the comments provide additional analysis and recommendations that the Panels believe are critical to EPA's consideration of this issue. The Panels would like to thank EPA for the 30-day extension to the original comment deadline.

As a threshold matter, the Panels note that EPA describes the preferred action under FIFRA 6(a)(2) as a "proposed policy statement." EPA cannot extend reporting requirements under FIFRA using this device. It is ambiguous whether EPA would complete its process in a formal notice-and-comment rulemaking, and the Panels note that EPA can only impose binding regulatory requirements through such a process.[2] Formal notice-and-comment rulemaking provides a level of detail and clarity, including statutory basis and economic and small business impact analyses, which the proposed policy statement does not. Because implementation of EPA's preferred alternative or any other alternative would impose new binding requirements on

[1] Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment. Federal Register Vol. 76, No. 117:35383. June 17, 2011.
[2] 5 U.S.C. 553.

manufacturers that are both different from existing requirements and punishable by civil and criminal penalties, the Panels believe that EPA must pursue a formal notice-and-comment rulemaking. Even then, the Panels believe that FIFRA 6(a)(2) cannot support such a regulation. Notwithstanding this threshold concern, in the attached document the Panels provide their views on clearer, more efficient means of collecting information on the presence of nanomaterials in pesticide products.

The Panels' comments emphasize that FIFRA 6(a)(2) is for reporting adverse effects, and the presence of nanotechnology is not an adverse effect. EPA should not try to misuse its authority regarding adverse effects to require re-reporting of information it may already have. EPA may have much of the information it wants in its product chemistry database and should review the data it already has and other available data in the first instance to determine whether it provides adequate information. EPA can do so without imposing any burden on registrants. This exercise should be completed before requesting resubmission or imposing more burden on registrants. Also, to the extent that current requirements are inadequate, EPA should utilize an appropriate combination of targeted data call-ins (DCIs) and revised product chemistry requirements to ask for additional information. Any such new requirements should be issued through legally appropriate procedures, including OMB approval under the Paperwork Reduction Act and, if substantive changes are being made to data requirements, rulemaking.

Finally, the Panels note that with this proposed policy statement EPA has initiated a process that will require considerable effort by EPA, the regulated community, and other stakeholders to achieve a mutual understanding of the scientific and legal issues around the use of nanomaterials in pesticide products. Indeed, any one of the questions articulated by EPA in the Federal Register notice could be the subject of a robust and informative dialogue. EPA's efforts to manage nanomaterials in pesticide products must proceed carefully so that the innovative potential of nanotechnology in the pesticide industry can be realized, while at the same time ensuring public confidence in nanotechnology oversight and management by both government and industry. As stated in the recent memorandum from the Executive Office of the President concerning federal oversight of nanotechnology:[3]

> *Advances in nanotechnology can drive economic growth, create quality jobs, and address a broad range of national challenges. Realizing these possibilities requires continued research, accelerated innovation, and flexible, adaptive, science-based approaches to regulation that protect public health, safety, and the environment while promoting economic growth, innovation, competitiveness, exports, and job creation.*

[3] Executive Office of the President. Memorandum for the Heads of Executive Departments and Agencies. June 9, 2011. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.

In the spirit of this guidance to federal agencies, the Panels strongly urge EPA to develop its regulations, policies, and analytical frameworks concerning management of nanomaterials in pesticide products in a transparent and consultative fashion with all stakeholders involved.

Sincerely,

Jay West
Senior Director
Chemical Products and Technology Division
ACC Nanotechnology Panel

Hasmukh Shah
Senior Director
Chemical Products and Technology Division
ACC Biocides Panel

Members of the ACC Nanotechnology Panel are Arch Chemicals, Inc., Arkema Inc., BASF Corporation, Bayer MaterialScience, Cabot Corporation, Cytec Industries, The Dow Chemical Company, DuPont, Evonik Degussa Corporation, Ferro Corporation, Procter & Gamble, and 3M.

Members and affiliates(*) of the ACC Biocides Panel are The Accord Group, AEGIS Environments, AkzoNobel Chemicals Inc., Albemarle Corporation, American Chemet Corporation, Arch Chemicals, Inc., Arkema Inc., Ashland Chemical, Bardyke Chemicals Ltd., BASF Corporation, Buckeye International, Inc., Buckman Laboratories, BWA Water Additives, Champion Technologies, Inc., Chemtura, Clariant Corporation, Clorox Company, Dial Corporation, Diversey Inc., The Dow Chemical Company, DuPont, Ecolab Inc., Elementis Chromium LP, Enviro Tech Chemical, Services, Inc., Exponent, FMC Corporation, GE Betz, Inc., ICL North America, International Specialty Products, ISK Biocides, Inc., Janssen PMP, Kemira Chemicals, Inc., Kimberly-Clark Corporation, LANXESS Corporation, Lewis & Harrison, LLC*, Lonza Inc., Lubrizol Corporation, Mason Chemical Company, Merichem Chemicals and Refinery Services, Microban International, Ltd., Milliken Chemical, Nalco Company, Nordox AS, Osmose, Inc., Peninsula Copper Industries, PPG Industries Inc., Procter & Gamble, Reckitt Benckiser, Inc., Rhodia Inc., SC Johnson & Son, Inc., SCM Metal Products, Inc., Scientific & Regulatory Consultants, Inc.*, Sostram Corporation, Stepan Company, 3M, Technology Sciences Group Inc.*, Thor Specialties, Inc., Toxicology Regulatory Services*, Troy Chemical Corporation, Verichem, and Viance, LLC.*

ATTACHMENT

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SCOPE OF REPORTING

Question 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?

The term "nanomaterial" is used widely and inconsistently. The Panels recommend that EPA consider providing a definition that makes clear whether a material that may be referred to as a "nanomaterial" is of regulatory interest. Drawing from the elements of a regulatory definition of manufactured nanomaterial developed by the International Council of Chemical Associations (ICCA),[4] as well as some additional considerations that provide greater focus, the Panels submit that EPA should implement the following considerations in order to clarify the materials that would be affected:

- Solid, particulate substances
- Intentionally manufactured at the nano-scale

[4] International Council of Chemical Associations. ICCA Core Elements of a Regulatory Definition of Manufactured Nanomaterials. November 22, 2010. See www.icca-chem.org/en/Home/Policy/.

- Consisting of nano-objects as defined by the International Standards Organization (ISO),[5] but without the word "approximately" to describe the size range. As discussed below, the Panels believe that for regulatory purposes, the ambiguity introduced by "approximately" will be problematic. Any meaningful compliance or enforcement standard based on particle size depends on the ability to measure with known accuracy and precision, an issue addressed in subsequent paragraphs. The Panels therefore recommend setting a lower limit of 1 nm and an upper limit of 100 nm.
- A mass-based cutoff for ISO nanomaterial content (per the previous bullet) to provide increased clarity on what is in scope and to ensure focus on those materials that have been the subject of nanomaterial discussions.
- Consideration of aggregates and agglomerates of nanomaterials
- Exclusion of aggregates/agglomerates if they cannot be readily broken down into nano-objects.

The Panels believe these additions are needed because the ISO definition of "nano-object" is based on size alone. EPA should include additional technical considerations that define the range of materials that would be affected more clearly and explicitly, and the list above is sufficiently robust to identify nanomaterials of interest. Once those materials are identified, other groups have identified more detailed lists of characteristics that EPA may find useful for understanding the relationship between physical chemical characteristics and unique properties. These include the Minimum Information on Nanoparticle Characterization (MinChar) initiative,[6] those listed in the guidance for the Sponsorship Programme for the Testing of Manufactured Nanomaterials of the OECD's Working Party on Manufactured Nanomaterials (WPMN),[7] and parameters to be published as TR 13014[8] by ISO Technical Committee 229 (Nanotechnologies). The elements considered by these groups are highly consistent and informative. The realistic potential for disintegration of aggregates and agglomerates to nanomaterials during normal use and handling throughout their lifecycle, including in biological and biospheric fluids, should also be taken into account.

Additional discussion of key concepts related to the bulleted list above follows. Additional discussion of the mass-based cutoff appears under question 4 below, as it responds directly to one of EPA's questions.

[5] International Organization for Standards. 2008. Nanotechnologies—Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate. TS 27687:2008. The Panels note that TS 27687 is currently under systematic review and that changes may be made in the future.
[6] See http://characterizationmatters.org/parameters/.
[7] Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme; First Revision. ENV/JM/MONO(2009)20/REV. June 2, 2010.
[8] The current working title of ISO/TR 13014 is "Nanotechnologies - Guidance on physico-chemical characterization of manufactured nanomaterials submitted for toxicological testing."

Removal of the term "approximately" from the ISO size range definition

The word "approximately" was removed in order to avoid an impermissibly vague regulatory definition. Regardless of the regulatory authority EPA selects to collect information regarding nanomaterials under FIFRA, the regulated community will be subject to civil and criminal penalties for non-compliance.[9] Due process requires that individuals should not face punishment for violating the law unless the nature of the prohibited conduct can be understood by a reasonable person. This is particularly true when criminal penalties may be imposed. An individual must be able to determine what is prohibited and what is required in specific situations and to not be forced to fear unpredictable prosecution.[10] Inclusion of the term "approximately" creates unreasonable uncertainty as to the lower and upper bounds of what EPA would consider nanoscale materials that require reporting or analysis. Vagueness with respect to the bounds of nanoscale materials lacks the specificity needed to provide fair warning to the regulatory community about the behavior required. Moreover, inclusion of such an ambiguous term creates the opportunity for arbitrary and discriminatory enforcement of the standard. As stated in Grayned, laws must provide explicit standards for those who apply them.

The Panels recognize that the upper limit of 100 nm is a common and internationally accepted limit for the definition of a nanomaterial, and a key review revealed that most novel size-dependent environment, health, and safety (EHS) properties of an important class of nanomaterials have been shown to occur below 30 nm.[11] Thus, 100 nm represents a conservative limit that, when combined with the other elements, allows the definition to include materials of interest. As analytical resolution, accuracy, and precision increase and the understanding of biological and toxicological implications of nanomaterials improve, the size dimensions in the definition might be adjusted.

The Panels believe that it will be important for EPA to be clear about how it expects the regulated community to measure particle size. It is widely recognized that different measurement methods can give different results. For example, it is possible that one method could determine that a material's average particle size is 90 nm, but another method could determine the size to be 110 nm. Would EPA consider both to be nanomaterials? While this example illustrates why others have used the word "approximately" in their definitions, the Panels believe that this flexibility will not work for regulatory purposes. Also, the existing FIFRA regulations provide

[9] FIFRA 14(a)(1), 14(b)(1)(A).
[10] "We insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972) (internal citations omitted).
[11] Auffan, M. et al. 2009. Towards a definition of inorganic nanoparticles from an environmental, health and safety perspective. Nature Nanotechnology 4:634. See also minutes of the November 3-5, 2009 FIFRA Scientific Advisory Panel meeting (Arlington, VA; SAP Minutes No. 2010-01) at page 8: "For nanosilver specifically, the literature does suggest that silver nanoparticles in the range of about 1 to 20 nm do possess the greatest quantum properties, are most optically active and may have the potential to induce the greatest toxicities."

specific guidelines for measuring required physical properties.[12] The Panels recommend that EPA provide a corresponding guideline for how registrants should determine particle size for the purpose of complying with any new data or reporting requirements. The Panels note that although the guidelines for pesticides require OPPTS 830.7520 for particle size, fiber length, and diameter distribution[13] under some conditions, OECD has concluded that the OECD guideline[14] upon which the OPPTS guideline is based requires modification before it can be used for nanomaterials.[15]

Clarity for the term "intentionally manufactured"

Intentionally manufactured nanomaterials are materials engineered to take advantage of their small size and novel properties, which are generally not seen in their conventional bulk counterparts. Novel properties are properties observed in nano-sized forms of the materials and that are unique to the extent that they would not be predicted simply by extrapolating from properties of the substance in its bulk form. Relevant properties could include altered physical chemical properties, hazard potential, or exposure potential. A focus on intentionally manufactured materials that exhibit novel properties at the nanoscale is consistent with several opinions on the focus of nanotechnology discussions, including those from:

- Executive Office of the President[16]
- United States Environmental Protection Agency[17]
- National Institute for Occupational Safety and Health[18]
- United States National Nanotechnology Initiative (NNI)[19]
- Health Canada[20]

[12] 40 CFR 158. Data Requirements for Pesticides; 40 CFR 161.190. Data Requirements for Registration of Antimicrobial Pesticides—Product Chemistry Data Requirements, Physical and Chemical Characteristics.
[13] U.S. EPA. 1996. Product Properties Test Guidelines: OPPTS 830.7520, Particle Size, Fiber Length, and Diameter Distribution. EPA 712-C-96-037.
[14] Particle Size Distribution/Fibre Length and Diameter Distributions. OECD Guideline for Testing of Chemicals No. 110. Adopted May 12, 1981.
[15] "TG110 - Particle Size Distribution/Fibre Length and Diameter Distributions, consists of two methods – A and B, the first of which is not applicable to nanomaterials, whilst the second would, with some modification (the inclusion of fibres of less than 5 microns in length and less than 100 nm in diameter), be applicable to nanoparticles as well as nanotubes and nano fibers. Studies should be carried out in order to extend its range of applicability to fibres with nano-scale dimensions. It is known that alternative methods for (nano) particle size distribution already exist, which should be taken into account if such studies are undertaken." See OECD. Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials. ENV/JM/MONO(2009)21, July 10, 2009.
[16] Executive Office of the President. Memorandum for the Heads of Executive Departments and Agencies. June 9, 2011. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.
[17] U.S. EPA. February 2007. Nanotechnology White Paper. EPA 100/B-07/001.
[18] National Institute for Occupational Safety and Health. 2009. Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials.
[19] U.S. National Nanotechnology Initiative. 2006. Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials.
[20] Health Canada. 2009. Interim Policy Statement on Health Canada's Working Definition for Nanomaterials.

- Australia National Industrial Chemicals Notification and Assessment Scheme[21]
- American Chamber of Commerce to the European Union.[22]

Substantiation for inclusion of aggregates and agglomerates

Consistent with good product stewardship, a definition of nanomaterials should consider aggregated/agglomerated materials. Some aggregated and/or agglomerated materials may be broken down into discrete nano-objects if subjected to sufficient shear forces. The level of disaggregation/disagglomeration will depend on the individual material, the magnitude of the shear forces, and the duration of time the forces are applied.

As with measurements of particle size, measuring the properties of aggregates and agglomerates can depend on the measurement method. As stated clearly in Annex A of ISO TS 27687:2008, particle measurements at the nanoscale depend strongly on the methods, equipment, dispersion unit, dispersion energy, media of dispersion, concentration of the nanomaterials, and stability of the generated aerosols.[23] As stated previously, in evaluating the realistic potential for disintegration of aggregates and agglomerates to nanomaterials, the magnitude of the shear forces and the duration they are applied must be representative of a realistic conditions across the life cycle of the material. Given the numerous measurement issues involved, the Panels believe that contemporaneous with issuing any mandatory reporting requirements for nanoscale materials, EPA should provide methodologies that are widely available and appropriate to the range of nanoscale materials that EPA expects it might encounter. EPA should be mindful of the ongoing work of ISO and the OECD WPMN in this regard.

Question 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?

The Panels believe that the requirements should apply to intentionally produced materials as described above (response to question 1) and should not apply to naturally occurring materials. From an EHS perspective, it should be recognized that exposure to naturally occurring nanomaterials has been ongoing for as long as the Earth has existed. From a practical perspective, EPA would be overwhelmed quickly by considering all natural and incidental occurrences of nanomaterials. It is important to remember that the EHS issues being addressed by the industrial, regulatory, and scientific communities pertain to intentionally manufactured nanomaterials of new composition or new nano-forms of existing materials that exhibit novel

[21] National Industrial Chemicals Notification and Assessment Scheme. 2010. Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials.
[22] American Chamber of Commerce to the European Union. 2010. AmCham EU Position on the European Commission Draft Recommendation on the Definition of the Term 'Nanomaterial.'
[23] International Organization for Standards. 2008. Nanotechnologies—Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate. TS 27687:2008.

properties. Including the qualifier "intentionally manufactured" will permit consideration of naturally occurring materials that may be further processed to impart novel properties. This again highlights the need for inclusion of the definitional elements listed above (response to question 1), which will help keep the materials affected focused and manageable. Also, EPA should consider whether the Toxic Substances Control Act's definition of "naturally occurring chemical substances"[24] could be applied to pesticide ingredients in order to achieve internal consistency.

Question 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?

The Panels recommend that EPA sharpen the meaning of "intentionally produced" to make it clear that not only is a material intentionally produced, but that it is intentionally produced to be at the nanoscale and to take advantage of properties associated with that scale.

Regarding the proposed consultation procedure, the Panels think that such a procedure should not be mandatory. It should be an option available to registrants or applicants who feel they need such a consultation to achieve clarity. Regulations should be sufficiently clear, without consultation, for regulated entities to ascertain what behavior is required.

Question 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?

Any sample of a solid particulate substance will contain a distribution of particle sizes, and that distribution may include particles in the 1-100 nm range. Thus, it is important to set a content threshold for reporting. The Panels believe that the percentage should be 10% by weight of nano-objects and their aggregates and agglomerates. The 10% weight threshold will effectively capture materials of the size range that have been the subject of nanotechnology discussions in various venues, while also providing increased clarity for manufacturers and users on what materials would be affected. Without such a threshold, all particulate matter may be considered a nanomaterial, as there is likely to be some small fraction of particulates in the nanoscale range.

[24] From 40 CFR 710.4: "(b) Naturally occurring chemical substances automatically included. Any chemical substance which is naturally occurring and: (1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (2) Which is extracted from air by any means, will automatically be included in the inventory under the category 'Naturally Occurring Chemical Substances.' Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals."

Any threshold chosen must be determinable with readily available and economical methods that provide consistent and reliable measurements. The Panels assert that the 10% weight cut-off is consistent with current detection capabilities and the sensitivity of reasonably available analytical instrumentation and methodologies that exist for particle characterization. As analytical resolution increases *and* understanding of the biological and toxicological implications of nano-objects improves, the 10% by weight threshold might be adjusted. The 10% weight threshold allows for a consistent and conservative path forward for considering nanomaterials that may be part of pesticide formulations. Again, the Panels emphasize that without a threshold, many conventional solid particulate substances would have some distribution in the nanoscale and thus be captured as nanomaterials.

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

The Panels believe that disclosure can be accomplished through EPA's product chemistry requirements for pesticides. The product chemistry forms can be revised to require disclosure of this information. Information on inert ingredients similarly can be disclosed through the inert ingredient approval process.

A manufacturer should not be penalized for not reporting information of which it is not aware. If a formulator purchases an ingredient, but is not informed about whether it contains nanomaterials, the formulator should not, nor can it, by the language of FIFRA 6(a)(2), be required to file a report under FIFRA 6(a)(2). This fact illustrates one significant limitation of using FIFRA 6(a)(2)—it burdens those registrants who possess information regarding the presence of nanoscale materials and rewards those who do not, potentially creating a disincentive for seeking such information. Some ingredient suppliers will have provided EPA with particle size information, and the formulators can identify the supplier on the Confidential Statement of Formula (CSF). In those situations, the Agency will be able to determine whether the formula contains or might contain nanomaterials. By using DCIs under FIFRA 3(c)(2)(B) and, in particular, data requirements established for the registration, re-registration, and registration review processes, EPA can obtain relevant information broadly with greater certainty and reliability.

Question 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?

As EPA considers refining the description of "nanoscale materials," the Panels respectfully point out the Agency's assumption that all materials that are defined as nanomaterials are "new" and are based on conventional (i.e., non-nano forms) of the same material. This is not always the case. Some materials that meet the newer definitions of nanomaterials have been in commercial use for decades, and there is no representative conventional (non-nano) counterpart. Materials such as carbon black and synthetic amorphous silica are and have always been nanostructured.

Some of these historic materials have robust datasets that demonstrate that they are safe when handled properly. The Panels suggest that EPA evaluate the need to include these historic materials as "nanoscale materials."

The Panels appreciate that the terms "unique or novel properties" can be subjective and recommends that EPA consider the list of elements on pages 1 and 2 of this attachment in refining the description of "nanoscale materials." For "unique or novel" properties, the Panels recommend that EPA consider whether or not a property is predictable based on information about bulk (i.e., non-nano) forms of the same substance. For example, some substances become more reactive as the particle size is reduced, and this is generally due to an increase in available surface area. Thus, it is possible to predict (either graphically or with an equation) how the two parameters are related based on known information about the substance. The Panels assert that such predictable properties are neither novel nor unique. However, other properties may change in ways that are presently not well understood and are not predictable. For example, the melting points of some metals (e.g., gold) decrease markedly as particles become nano-sized. Clearly this is novel, but it is unlikely to impact the EHS properties of the material. Therefore, it is worth noting that a novel change in one property does not mean that all physical properties or other properties related to EHS considerations also have novel or unique changes. The Panels note that the comments here are consistent with the recent guidance from the Executive Office of the President which states "A focus on novel properties and phenomena observed in nanomaterials may ultimately be more useful than a categorical definition based on size alone."

Due to the difficulty of interpreting or defining "novel and unique properties," EPA should consider a review of currently available data that helps to further define what is considered within the scope of the phrase. As with the example above, an increase in surface reactivity may not be considered a novel property, as it can be explained by the understanding of the material. However, if EPA considers such a phenomenon to be of interest for reporting, such expectations would need to be defined explicitly. Thus, if EPA elects to pursue an approach that includes "unique or novel properties," it must provide sufficient clarity to the regulated community to predict what properties, or changes in properties, the Agency would believe are "unique or novel." Predictability is critical, as the regulated community must not be forced to guess what behavior is required or prohibited when civil and criminal penalties are possible.

Question 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?

Unfortunately, the current set of definitions developed or being considered by the regulatory community, industry, and standards bodies lacks consistency. The Panels assert that by addressing the list of elements on pages 1 and 2 of this attachment and providing the additional clarification recommended in the response to question 6 immediately above, concerns about

inconsistency with other definitions will be mitigated. Doing so would capture materials of interest to EPA while also providing clarity and predictability to the regulated community.

Question 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)?

Risk is a function of hazard and exposure. Knowledge of both is needed to assess risk. In the absence of data, reasonable science-based estimates can be used. This is a standard practice for all chemicals, not just those that have a size in the nanoscale.

Implicit in EPA's question is an assumption that the presence of a nanomaterial in a pesticide product is hazardous. This is not necessarily true. However, for a "particular nanoscale material," EPA can be informed about the potential hazards of the nanomaterial if they have nanomaterial-specific data, data on analogous nanomaterials, data on the non-nano form, modeling information, or knowledge of the chemistry of the substance that may lead to a prediction of the degree of hazard, if any. Furthermore, an understanding of the specific properties of a nanomaterial may facilitate appropriate read-across to data on non-nano forms of the material.

Nanomaterials are a subset of chemicals and, while they share a commonality of small size, there are other unique properties that make generalizations about nanomaterials, as a single broad class, difficult. However, just as it may be possible to make some generalizations across more specific chemical classes, the same may be possible for narrow classes of nanomaterials such as soluble and insoluble metal oxides. As pointed out previously, understanding the potential for disintegration of aggregates and agglomerates in biological and biospheric fluids is also an important consideration.

For the purposes of answering EPA's question about tests that could provide useful information the Panels recommend that EPA consult the considerable work of the OECD WPMN and ISO in this regard. Notwithstanding the earlier note about OECD TG 110, the OECD WPMN has said that many TGs are applicable to nanomaterials, with conditions, and OECD is embarking on an active program to develop sample preparation and dosimetry guidance that address issues associated with specific tests.[25] The Panels emphasize that any data requirements and the product

[25] "Many of the OECD Test Guidelines are applicable, with conditions in some cases, while some are inadequate for testing Manufactured Nanomaterials (MN) as measuring, dosing, delivery and tracking nanomaterials are not reliably accomplished at this stage. Therefore, the review of OECD Test Guidelines reinforced the need for a **guidance document(s) for sample preparation and dosimetry**. It suggests that the guidance document(s) be developed as a new document(s), and be independent from the existing OECD guidance documents." (emphasis in original). OECD. Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials. ENV/JM/MONO(2009)21, July 10, 2009.

risk assessment should be informed by the potential routes of exposure, which will vary by material and application.

Regarding EPA's question about bioavailability, the Panels note the growing recognition that toxicological studies conducted with "neat" or "pure" nanomaterials may not be representative of the form in which materials are actually used in products and/or encountered by the body and the environment. Nanomaterials interact with various environmental components (e.g., water and other solvents, proteins and other organic matter), reducing the potential for exposure to "neat" or "pure" nanomaterials. Thus, the results of such studies may represent neither the hazards of the nanomaterials in use, nor the way in which they appear in the environment. This is a particular concern with older literature in which these issues were not as well appreciated and accounted for in experimental designs. In addition, EPA should consider that bioavailability may be a function of surface area. An ionic/molecular form of a material may be more bioavailable than a nano form, and a nano form may be more bioavailable than a non-nano form. The Panels recommend that EPA remain mindful of these issues as it considers the relevance of the toxicological literature when evaluating pesticide products that contain nanomaterials.

PROPOSED APPROACHES FOR INFORMATION COLLECTION

Question 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?

If a nanoscale material (defined using the suggested elements on pages 1 and 2 of this attachment) has properties that, for purposes of risk assessment, are essentially the same as larger sized materials of the same substance, it is reasonable to conclude that the nano and non-nano forms are similar from a hazard perspective. If the exposure routes are comparable between the two forms, the risk profile is likely similar as well. For the purposes of risk assessment, it will be useful for EPA to understand why a particular material is being introduced at the nanoscale in order to understand what properties might be influenced.

The Panels note that EPA has access to a large body of information in the public domain such as literature, many national and international databases, voluntary submissions (e.g., the "FYI" program under TSCA Section 8(e)), regulatory submissions made under TSCA and other laws, and information generated and shared through international programs such as the OECD WPMN. We encourage EPA to mine these resources for useful information that is of high quality as it carries out its duties and assesses future data needs.

Question 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?

EPA previously addressed issues related to how it should regulate active ingredients with similar chemical structures but potentially different toxicities. For example, EPA raised questions as to whether purified isomers of registered active ingredients should be considered as new active ingredients or simply as new formulations, including consideration of economic factors. [26] The Agency eventually decided that such purified isomers are not new active ingredients,[27] but relied upon bridging data between the originally registered form and the purified form, citing structural similarity as the basis. This approach applies equally to mammalian toxicity concerns as well as for environmental fate and effects.[28] The purified forms were determined to be substantially similar to the originally registered form because the mechanisms and types of activity were similar, even when differences existed in absolute toxicity values. In the case of nanoscale ingredients, when properties and relevant evidence indicate substantial similarity between nano and non-nano forms and exposures are comparable, similar to what was shown with the purified isomers, it is reasonable to conclude that there is comparable risk. Relevant evidence could include appropriate data of sufficient quality to support bridging but should not require a complete database. Where the evidence supports similar mechanisms of toxicity and similar exposures, EPA should conclude that the nano forms of both active and inert ingredients are substantially similar and can be registered as such.

As noted earlier, the Panels also remind EPA that presently registered pesticide products may contain nanoscale ingredients that have been in use for many years, even decades, before the term "nanoscale" came into usage. They may have been described as "ultrafine," for example. EPA should be aware of this fact and take into account the safety record of the use of such ingredients.

Question 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?

EPA proposes collecting information regarding nanoscale materials for FIFRA and PRIA purposes under the FIFRA 6(a)(2), which requires a pesticide registrant that has additional factual information regarding unreasonable adverse effects on the environment of the pesticide to report it to EPA. EPA's alternative collects information on the presence of nanoscale materials

[26] Pesticides; Request for Comment on Pesticide Registration Proposal for Isomeric Active Ingredients. *Federal Register* Vol. 64, no. 81, p. 22863, April 28, 1999.
[27] Mefenoxam; Pesticide Tolerance. *Federal Register* Vol. 66, no. 180, p. 47994, September 17, 2001.
[28] See the Environmental Fate and Effects Division interim policy on stereoisomers at www.epa.gov/oppefed1/ecorisk_ders/stereoisomer_policy.htm.

under FIFRA 3(c)(2)(B)(i), which permits EPA to determine that additional data are required to maintain existing registrations. In addition to these mechanisms, EPA can collect information regarding the presence of nanoscale materials in pesticide formulations during the initial registration, registration review (FIFRA 3(g)), and re-registration (FIFRA 4) processes. During each of these processes, EPA has the ability to require information necessary to meet the statutory standard of no unreasonable adverse effects. Each of these processes is ongoing, and does not require additional regulatory authority or policy interpretations to implement.

EPA may have much of the information it wants in its product chemistry database and should review the data it already has to determine whether it provides adequate information. EPA can do this without imposing any burden on registrants. If after reviewing this information EPA determines that it needs additional information, the Panels suggest that EPA, following appropriate processes, utilize an appropriate combination of targeted DCIs and revisions to its product chemistry requirements to ask for additional information it now considers important. This will allow collection of information on particular products in an organized, appropriate manner.

The Panels note that the phrase "data showing that size, especially when reduced below approximately 100 nm, may alter the manner in which materials behave" is one-sided and does not consider that materials behaviors may not change at the nanoscale. While the phrase is accurate that particles below 100 nm may behave differently, the opposite is also accurate. The Panels also believe that the response to EPA's bioavailability question (question 8 in the previous section) is also germane to this question.

ALTERNATE WAYS TO OBTAIN INFORMATION

Question 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?

EPA has described a perspective that incorporates some of the scientific information about nanomaterials describing benefits and concerns. Implicit in the summary is a conclusion that because there are changes in physical properties, there is likelihood that there are also undesirable changes in EHS risks. As noted above, some of the literature that suggests such issues draws conclusions based on forms of nanomaterials that are not representative of the forms actually used or encountered. This is not to say that nanomaterials are categorically not hazardous or never have unique hazards compared to non-nano forms. Some nanomaterials are likely to be hazardous, and it is also likely that some nanomaterials will have unique hazards. There could be more of a balance in how EPA has characterized the EHS concerns around

nanomaterials. For example, EPA did not cite any literature where concerns were not observed. The Panels note that the literature is acknowledged to be deficient in the publication of results where no effects were observed. Papers where effects are observed are generally considered more noteworthy, and such under-reporting likely results in what appears to be cause for potential concern.[29]

The Panels believe that the approach EPA takes will have a significant impact on the perception of risk and that the 6(a)(2) option is the worst of all possible options in this regard. The proposal as stated in the draft policy position is that registrants would be required to report the presence of a material that may actually provide EHS benefits as an adverse event. Indeed, even the plain language of this section of the law is a problem, a fact that EPA does not appear to appreciate by stating that 6(a)(2) is its preferred approach. Utilizing an appropriate combination of targeted DCIs and modification of EPA's product chemistry data requirements is a more appropriate approach.

FIFRA section 6(a)(2) requires reporting of unreasonable adverse effects or information that would raise concerns about the continued registration of the pesticide product. EPA states in this proposed policy that the mere presence of nanoscale ingredients does not mean that EPA believes that all nanoscale materials pose a risk. The Panels appreciate this acknowledgement. Since not all nanoscale materials pose a risk, similarly the presence of nanoscale materials in a pesticide product does not necessarily raise questions relevant to the continued registration of a product. Therefore, the FIFRA 6(a)(2) mechanism may not be a legally appropriate tool to obtain such information. EPA's proposed policy statement does not offer sufficient description of the statutory basis of a requirement to require the reporting of nanoscale materials under FIFRA 6(a)(2) to ascertain whether the Agency believes that such information may be required as "unreasonable adverse effect" information. An analysis of statutory basis as part of a proposed regulation should be provided before EPA imposes a reporting requirement. Moreover, assuming that 40 CFR 159.158(a) applies, EPA has not justified that the presence of nanoscale materials is relevant to the assessment of risks or benefits.

By contrast, the use of the DCI authority is preferable if, after an assessment of already available information, it is deemed necessary. A DCI does not label the reported data as an indication of unreasonable risk. More importantly, through DCIs, EPA would be able to focus on a limited set of data elements (such as particle size, shape, and distribution) targeted to those registrants with registrations most likely to include nanoscale ingredients. At that time, EPA would be expected to explain why those elements are important and how it will use the information. Also important is the opportunity for the regulated community to be able to offer comments on how the data request can be improved.

[29] See for example Wandall, B., Hansson, S.O., and Rudén, C. 2007. Bias in toxicology. Archives of Toxicology 81:605–617 and Young, N.S., Ioannidis, J.P.A., and Al-Ubaydli, O. 2008. Why Current Publication Practices May Distort Science. PLOS Medicine 5(10): 1418-1422.

Question 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.

EPA has an obligation to meet the statutory standard for registering a pesticide. The Panels appreciate EPA's need to understand aspects of a product that are likely to have an effect on a pesticide product's performance and safety. In some cases the presence and attributes of nanoscale materials therein may be relevant to EPA evaluating the pesticide against the safety standard.

Question 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.

EPA proposes collecting information regarding nanoscale materials for FIFRA and PRIA purposes under the FIFRA 6(a)(2), which requires a pesticide registrant who has additional factual information regarding unreasonable adverse effects of the pesticide on the environment to report it to EPA. The term "unreasonable adverse effects on the environment" is defined as: "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."[30] There are several limitations with this approach, and those limitations are described in the paragraphs below.

EPA cannot avoid stigmatizing nanotechnology with this approach. The FIFRA 6(a)(2) provision is both called the "unreasonable adverse effects" reporting provision and is thought of by the public as such. EPA states that the information it is considering seeking under this nanomaterials policy would not be limited to information about direct adverse effects, but would be broadly interpreted to include information relevant to determining whether a pesticide has the potential to cause unreasonable adverse effects. Nonetheless, the public are interested in information reported under FIFRA 6(a)(2) as it is often considered by them to be negative information about adverse effects of a pesticide.

EPA also has considered certain information safety and efficacy information reported by registrants under 6(a)(2) as being not subject to CBI claims (see, e.g., Class Determination 1-99). Requiring submission of nanoscale information under 6(a)(2) could render broad classes of business information regarding innovative nanomaterial products subject to public disclosure.

Using FIFRA 6(a)(2) will not yield all the information EPA wants. FIFRA 6(a)(2) only applies to information that a registrant has, and does not require registrants to seek information that would

[30] FIFRA 2(bb).

be responsive. This approach can encourage ignorance of information, discourage scientific analysis, and disincentivize innovation.

Although EPA explains that it has sought information not directly demonstrating adverse effects under this provision, the reporting provision's requirements are plain. It does not encompass purely neutral or beneficial information if that information does not contribute towards an analysis of the pesticide's unreasonable adverse effects on the environment. The definition of "unreasonable adverse effects" itself includes economic, social, and environmental benefits, is a qualifier to unreasonable risk to man or the environment, and is not a catch-all that permits EPA to require reporting broadly of neutral or beneficial information regarding pesticide products. Therefore, unless EPA can demonstrate how information about the presence of active or inert nanoscale materials in a pesticide product would be used in an analysis about the continued registration of a product, that information is not appropriately captured under FIFRA 6(a)(2).

Question 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?

The Panels feel that it is impossible to avoid the mischaracterization if EPA chooses to use the FIFRA 6(a)(2) option. There are stakeholders who have argued that nanomaterials are *de facto* dangerous and have called for bans despite a wealth of scientific data to the contrary and despite evidence of widespread benefits to society and the environment. Furthermore, the Panels believe that using the "unreasonable adverse effects" mechanism when other mechanisms are clearly available would be contrary to the guidance provided in the previously referenced memorandum from the Executive Office of the President[31], which states:

> *Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful. In this regard, identification of specific risks in the context in which they arise—based on scientific evidence to support that judgment—will help to ensure that perceptions of specific nanomaterials are based on scientific evidence rather than unsupported generalizations.*

By using the 6(a)(2) mechanism, the Panels believe that EPA would be making the kind of "scientifically unfounded generalization" that is wholly inconsistent with the direction provided in the memorandum.

Should EPA choose to use FIFRA 6(a)(2) authority to gather information about nanomaterials, the Agency will not be in a legally defensible position. This would be a misuse of EPA's statutory authority, even if done through rulemaking, which would subject EPA to legal

[31] Memorandum for the Heads of Executive Departments and Agencies. June 9, 2011. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.

challenge. Such controversy is entirely unnecessary, as there are other mechanisms available to obtain information on the composition of pesticide products.

Question 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?

The Panels believe that the burden of seeking the information EPA specifies is not going to be any different whether it is requested through a DCI, by considering it an "adverse effect," or by changing the OPP product chemistry requirements. Therefore, the burden must be assessed regardless of the procedural mechanisms EPA seeks to employ. EPA could keep the burden low by ensuring that it provides a clear description of what materials are within the scope of the requested information. EPA could further reduce the burden by focusing on resources that may help in the understanding the relationship between physical chemical characteristics and unique properties. The Panels provide recommendation in both regards in the response to the first question of this comment package. Finally, the Panels believe that searching the National Pesticide Information Retrieval System database for information generated according to test guideline 830.7520 for information (or information gaps) that could, along with other information, help the Agency determine which products should receive DCIs.[32]

The Panels agree that in all cases, EPA should first focus on what specific scientific information it needs in order to avoid unnecessary and costly analysis and reporting tied to no clear purpose or question. For example, while nano-silver products are clearly of interest to EPA and, while the Panels understand that interest, the Panels believe that most, if not all, of the efficacy and important toxicology is based on the silver ion, which is well understood.[33] Since use volume can be a loose surrogate for exposure potential, it may be possible to set a threshold that if exceeded would trigger the requirement to report whether a pesticide product contains nanomaterials.

Question 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

[32] U.S. EPA. 1996. Product Properties Test Guidelines: OPPTS 830.7520, Particle Size, Fiber Length, and Diameter Distribution. EPA 712-C-96-037.

[33] Landsdowne, A.B.G. 2010. Silver in Healthcare: Its Antimicrobial Efficacy and Safety in Use. The Royal Society of Chemistry (Cambridge); Sondi, I. and Salopek-Sondi, B. Silver nanoparticles as antimicrobial agent: a case study on E. coli as a model for Gram-negative bacteria. Journal of Colloid and Interface Science 275(1): 177-182; Dowling, D.P. et al. 2001. Deposition of anti-bacterial silver coatings on polymeric substrates. Thin Solid Films 398-399: 602-606; U.S. EPA. 1993. R.E.D. Facts: Silver. EPA-738-F-93-005.

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?

Size is not a hazard. Requesting information only about size has limited utility. EPA must focus on properties of interest that could pose a potential health and/or environmental risks. It is unclear that identifying all nanomaterials used in pesticide products is useful, and EPA could provide clarity by explaining what it would do with such knowledge.

Physical property information may be useful, and a short list of properties has been identified by some leading groups through the MinChar Initiative, OECD WPMN, and ISO TC 229 among others. The burdens do need to be considered, and the value will be determined in large part by what EPA will do with the information, which the Panels hope and expect will be explained.

MECHANISMS FOR IMPOSING DATA REQUIREMENTS

Question 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?

The Panels agree that reporting and data requirements for pesticides containing nanoscale materials should be done through a formal rulemaking process, in contrast to a policy statement. In establishing appropriate data requirements, the Agency should determine and then explain how the data will be used in the assessment of risk. Simply asking for data without an understanding as to how it will be used would be a resource drain on both EPA and the regulated community. Nanoscale materials are heterogeneous, as are conventionally scaled materials, and EPA should evaluate the same kinds of studies that are used for conventional materials. No additional data requirements over the current 40 CFR 158 rules are warranted. The Panels strongly recommend that EPA consult the considerable work being done by groups like the OECD WPMN, ISO, and others on the appropriateness of and, in some cases, necessary modifications to, existing test guidelines when assessing nanomaterials.

The Panels are aware that EPA is evaluating nanomaterials as part of its ToxCast™ program.[34] ACC has long supported the development, standardization, and validation of alternative toxicity test methods. The Panels believe that such tools can provide important screening information, but there is still a need for tools and methods to interpret the information from such tests in the

[34] Gangwal, S. et al. 2011. Informing selection of nanomaterial concentrations for ToxCast *in vitro* testing based on occupational exposure potential. Environmental Health Perspectives. On line July 25, 2011.

context of regulatory decision making and quantitative risk assessment. We would welcome the opportunity to better understand EPA's work in this area and share our perspectives on how such tools can be developed to reflect real world exposure scenarios and contribute to understanding potential human health and environmental risks.

Question 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?

All three considerations are important, and EPA can balance all of them by selecting the appropriate information collection tool and tailoring it appropriately to manage these concerns. EPA is required to review current pesticides and does so through registration review and re-registration. In these processes EPA can evaluate whether specific information regarding particle size is needed to assess the continued registration of products. Equity and burden minimization can be managed by imposing similar, targeted data requests to similarly situated registrations for which EPA has articulated a rational basis for seeking nanoscale ingredient information.

Marketplace equity and minimizing burdens on regulated entities can also be well-managed through a targeted DCI. A DCI would apply to all similarly situated registrants, and EPA can minimize the burdens by carefully selecting both the categories of information it seeks and the categories of registrants it solicits for additional information. The Panels reiterate that using the Agency's preferred 6(a)(2) approach meets none of these considerations. EPA would only get information about nanoscale materials in products when the registrant already possesses that information, which is inequitable, as it imposes varying burdens on select registrants based on how much information each registrant happens to possess. Because it is inequitable, the 6(a)(2) approach could result in a patchwork of information insufficient for the Agency to accurately assess the role of nanoscale materials in registered products.

CLASSIFICATION OF APPLICATIONS UNDER FIFRA AND PRIA

The Panels note that in the Federal Register notice EPA asks no questions about the two "initial presumptions" that underpin the proposed classification policy.[35] The Panels are concerned about these starting points and EPA's lack of analysis of their impact on the regulated community. The Panels believe that a classification policy based on these two presumptions would create a highly unpredictable and functionally arbitrary regulatory environment. It is not unreasonable to be concerned that the reliance on rebuttable presumptions and case-by-case analysis for doing so could lead to significant delays in time to market, inconsistent results among registrants, and inconsistent results among various products containing the same nanoscale ingredient.

[35] From page 35392, the first presumption is "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" and the second is "that nanoscale active and inert ingredients are potentially different even from other, already registered nanoscale versions of the same ingredients."

Registrants need to be able to assess, in advance of submitting a registration, whether their proposed product is under certain PRIA categories for the purposes of evaluating Agency review time and knowing the applicable fee category, both of which are essential pieces of business information.

The Panels note that EPA has not treated the size of active or inert ingredients as a basis for determining that such an ingredient is new, and EPA has not adequately justified this proposed new presumption. EPA must do so before undertaking such a departure from existing practice. The proposed policy further suggests that any change in size or structure, once an ingredient is within the nanoscale range, renders that ingredient presumptively new. Given the lack of basis and the potential impact should EPA implement a classification policy based on these presumptions, the Panels believe that EPA must approach the classification of applications through a robust notice-and-comment rulemaking process. The Panels would expect an appropriate analysis of the statutory and scientific basis, as well as economic and small business impacts.

As noted earlier, presently registered pesticide products may contain nanoscale ingredients that have been in use for many years, even decades, before the term “nanoscale” came into usage. They may have been described as “ultrafine,” for example. EPA should be aware of this fact and take into account the safety record of the use of such ingredients.