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The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides

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EXECUTIVE SUMMARY

As applied to pesticides, the new and developing area of nanotechnology has the potential to bring real benefits, but also regulatory challenges. Reportedly, it has already begun changing the nature of some pesticides. There are consumer products on the market today using engineered nanoparticles of active ingredients such as silver to achieve antimicrobial effects, and many more are likely.[2] Even as these consumer products are introduced, agricultural chemical producers are developing new pesticide products using nanotechnology to enhance the effectiveness or delivery of those pesticides. Among the uses of nanotechnology in agriculture currently being explored are agrochemical delivery (delivery of pesticides and other chemicals only when needed or for better absorption), nanosensors, and new or modified active pesticidal ingredients.[3]

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the U.S. Environmental Protection Agency (EPA) has the authority and responsibility to determine whether the benefits of pesticidal products developed using nanotechnology (referred to herein as "nanopesticides") outweigh any risks, and to determine the conditions under which a nanopesticide may be registered so as to limit potential risks. EPA has stated that "[i]t is expected that pesticide products containing nanomaterials will come under FIFRA review and registration." Yet it has also acknowledged questions about how FIFRA can be applied to

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1 This report was prepared by James C. Chen, Crowell & Moring, LLP; Larry Culleen, Arnold & Porter; Mark Duvall, The Dow Chemical Company; Tricia A. Haught, Day, Berry & Howard LLP; Warren U. Lehrenbaum, Pillsbury Winthrop Shaw Pittman, LLP; Douglas T. Nelson, CropLife America; Patrick J. Paul, Snell & Wilmer L.L.P.; Rebecca Wright Pritchett, Sirote & Permutt, P.C.; and Alan J. Sachs, Beveridge & Diamond, P.C. Mark Duvall served as the FIFRA Team Leader.

2 *See, e.g.*, Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, A Nanotechnology Consumer Products Inventory, available at http://www.nanotechproject.org/index.php?id=44.

3 *See, e.g.*, Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, Inventory of Agrifood Nanotechnology, available at http://www.nanotechproject.org/index.php?id=50; Center for Science, Technology, and Public Policy, University of Minnesota, "The Nanotechnology-Biology Interface: Exploring Models for Oversight, September 15, 2005, Workshop Report," available at http://www.hhh.umn.edu/img/assets/9685/nanotech_jan06.pdf.

nanopesticides, such as whether use of a nanoscale material results in a change to a pesticide product already registered under FIFRA.[4]

This paper addresses that and other challenging issues relating to the application of FIFRA to nanopesticides. It discusses the extent to which FIFRA and EPA's implementing regulations and programs are adequate to address the regulatory challenges of such products.

In summary, EPA has considerable authority under FIFRA to prohibit, condition, or allow the manufacture and use of nanopesticides. Its regulatory tools include regulation of pre-registration research and development (R&D) through experimental use permits (EUP); requirements for pre-registration testing; the registration requirement, which requires development of data and can impose limits on the use and handling of a nanopesticide; requirements for registrants to submit post-registration adverse effects information; possible requirements for post-registration testing; and reregistration requirements. Additionally, EPA has strong enforcement options under FIFRA to proceed against unregistered nanopesticides or those found to cause unreasonable adverse effects on human health or the environment. EPA may therefore prohibit the use of nanopesticides presenting unreasonable adverse effects, and may restrict other nanopesticides so as to ensure that risks do not become unreasonable.

I. GENERAL COMMENTS ON FIFRA REGULATION OF NANOPESTICIDES

A. FIFRA Provides Considerable Authority to Regulate Nanopesticides

FIFRA offers EPA ample statutory authority to regulate nanopesticides. This authority covers the entire scope of regulatory interest, from pre-registration research and development, to registration, through post-registration marketing and use.

As discussed in greater detail below, under FIFRA Section 5, EPA regulates pre-registration activities such as R&D. For example, EPA currently regulates R&D on conventional pesticides through EUPs. Pesticide developers must notify EPA and obtain a permit prior to conducting R&D on pesticides except where the Agency has expressly chosen to exempt certain classes of R&D. EUPs themselves can be tailored to address the particular circumstances of the R&D activities or the material involved. Thus, EPA can ensure that the risks of testing unregistered nanopesticides are managed appropriately.

The degree of control that EPA has under FIFRA is in marked contrast to the Agency's regulation of R&D under the Toxic Substances Control Act (TSCA). For example, under the premanufacture notice (PMN) R&D exemption, developers of new chemical substances have no obligation to notify EPA of any aspect of their R&D activities. EPA has limited means of controlling research risks beyond enforcing certain minimal requirements. Instead, the TSCA regulation simply requires that hazards are communicated; that the amount

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[4] EPA, Science Policy Council, "Nanotechnology White Paper" (external review draft) (Dec. 2, 2005) at 26, 27, available at http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf.

produced for R&D not exceed that reasonably necessary for the research purpose; that a technically qualified individual supervise the research; and that records are maintained.[5]

As noted above, EPA has chosen to promulgate several limitations on the requirement to obtain an EUP prior to conducting R&D. Stringent controls have not been deemed necessary in the past for such research on conventional pesticides; however, they may or may not be necessary for R&D on nanopesticides. Theoretically, workers would be protected by applicable Occupational Safety and Health Administration (OSHA) requirements. Nevertheless, EPA could cut back on or eliminate its self-imposed restrictions on the scope of the EUP requirement with respect to nanopesticides if appropriate.

EPA's most powerful tool for controlling the potential risks posed by nanopesticides is the registration requirement. Registration review provides EPA with the opportunity to prohibit, condition, or allow the manufacture and use of nanopesticides and prescribe the conditions of that manufacture or use. The registration requirement in FIFRA Section 3 is backed up by strong enforcement powers that EPA can exercise over unregistered pesticides under FIFRA Sections 12, 13, 14, and 19.

The registration requirement expressly provides EPA authority to require the generation of data necessary for risk assessment on the candidate nanopesticide; to conduct a risk assessment balancing the risks and benefits of the nanopesticide; to prohibit the use of a nanopesticide that is determined to present unreasonable adverse effects to human health or the environment; and to condition the use of a nanopesticide to ensure that it does not present the threat of unreasonable adverse effects. The authority afforded under FIFRA is far more flexible than that provided for existing chemicals under TSCA Sections 4, 6, and 7. Instead, EPA's FIFRA authority is more akin to EPA's authority under TSCA Section 5(a)(1) regulating new chemicals, but is even more comprehensive than this PMN authority.

EPA's authority to regulate nanopesticides under FIFRA continues post-registration as well. After a period of years, reregistration is required under FIFRA Sections 3(g) and 4. EPA can require post-registration testing of nanopesticides under FIFRA Sections 3(c)(2)(B) and 4. Nanopesticide registrants remain under an obligation to notify the Agency of adverse effects discovered after registration under FIFRA Section 6(a)(2). If EPA should determine that the balance of risks and benefits of a nanopesticide has shifted since its original risk assessment, the Agency has a variety of tools to halt further use of the nanopesticide under FIFRA Sections 12, 13, 14, and 19.

B. Nanopesticides Provide EPA with Regulatory Challenges

Although the Agency has considerable authority to regulate nanopesticides under FIFRA, exercising that authority appropriately will require rethinking its decisions on issues that are settled with respect to conventional pesticides. Among the challenges are the following:

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5 40 C.F.R. §§ 720.3(cc) and (ee), 720.36.

- Nano versions of registered conventional pesticides raise questions as to whether new registrations are needed under current requirements, although this question is likely to be more easily resolved under TSCA.

- EPA may want to reconsider its exemptions from EUP requirements for nanopesticides.

- EPA may need to identify an appropriate data set for EPA's risk assessment of nanopesticides.

- EPA may want to develop registration requirements specifically for nanopesticides.

II. EPA AUTHORITY TO REGULATE NANOPESTICIDES PRIOR TO REGISTRATION

EPA has authority to regulate any substance or mixture of substances intended to be a pesticide prior to registration. Existing authorities under FIFRA in the pre-registration regulatory arena do not distinguish regulated products by size, but by intended function (*i.e.*, as a pesticide). Accordingly, the Agency is well poised to regulate nanopesticides prior to their registration either immediately or upon modification of existing regulations or policies.

A. EPA's EUP Authority

EPA's authority to regulate pre-registration activities for pesticides has generally focused on R&D activities, particularly with respect to those persons wishing to accumulate the necessary information in order to register a pesticide under FIFRA Section 3. Under FIFRA Section 5(a), EPA has established a number of requirements for the pre-registration activities under an EUP. These requirements are set forth generally in the regulations at 40 C.F.R. Part 172.

Many of the requirements of Part 172 may apply directly or with some minor modification to nanopesticides. For example, EPA has prescribed data submission requirements for EUPs at 40 C.F.R. Section 172.4(b). Since those requirements set forth the information needed by the Agency in general terms, EPA likely would not need to conduct additional rulemaking to address EUP data requirements for nanopesticides. Regardless, EPA may still wish to review those requirements in light of the unique properties of nanopesticides and make modifications as necessary. Specifically, as a matter of practical application, EPA may want to notify applicants of the specific nanopesticide information that the Agency believes is appropriate in order to meet the requirements of 40 C.F.R. Sections 172.4(b)(1)(iii), (vi), and (vii) regarding the details of the testing, scope of testing to be conducted, purpose of the testing, any prior testing or knowledge of existing properties or toxicity of the nanopesticides, and the planned storage and disposal plans for the nanopesticides. Section 172.4(b)(1)(viii) provides EPA with sufficient authority even beyond the scope of the information described, in that this provision allows EPA to seek any "other additional pertinent information as the Administrator may require." Accordingly, EPA has the authority in existing regulations to require additional

testing or information necessary to appropriately review any EUP application associated with nanopesticides.

In addition, EPA can solicit public comment and even hold a public hearing on any EUP permit applications that may be of regional or national significance.[6] On several occasions EPA has solicited public comment on EUP applications related to small-scale field testing of genetically engineered microbial pesticides,[7] and the Agency may wish to do so for nanopesticides as well.

Based on the information submitted under 40 C.F.R. Section 172.4(b) and the Agency's analysis of such information, EPA may impose appropriate limitations on a nanopesticide's EUP to address any potential risks.[8] As to whether an EUP would be needed for a nanopesticide for which a macro version has been registered, see the discussion of pesticide registration below.

As an alternative to direct application of existing provisions, should EPA determine that nanopesticides warrant specific regulatory provisions, the Agency may wish to consider a special nanopesticide provision on EUPs that addresses the unique characteristics of those substances. EPA has done this in the past with genetically modified microbial pesticides.[9] EPA would need to support the decision for special provisions with evidence demonstrating this need. Given the new and unique properties of nanopesticides, this would likely not be an issue.

B. Exemptions from EUP Requirements and Corresponding Controls

Currently, under 40 C.F.R. Section 172.3, certain types of R&D activities are exempt from the EUP requirements. Examples include tests conducted in laboratories or greenhouses and replicated field trials or other tests intended solely to assess a pesticide's potential efficacy, toxicity, or other properties.[10]

Given the unique properties of nanopesticides, EPA may wish to reconsider that general presumption as applied to these new types of pesticides, especially with respect to tests assessing toxicity. EPA has expressly reserved the right to revoke the general presumptions on a case-by-case basis. Specifically, pursuant to 40 C.F.R. Section 172.3(e), EPA may require that any type of testing for a particular pesticide or class of pesticides, including tests generally exempt from EUP requirements, be conducted under an EUP through notification to the pesticide developer. Given the unique characteristics of nanopesticides, EPA may wish to consider

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6 40 C.F.R. § 172.11.

7 *See, e.g.*, 69 Fed. Reg. 23193 (Apr. 28, 2004); 66 Fed. Reg. 30458 (June 6, 2001).

8 *See* 40 C.F.R. § 172.5(c).

9 *See, e.g.*, 40 C.F.R. Part 172, Subpart C.

10 *See, e.g.*, 40 C.F.R. § 172.3(b) and (c).

invoking the provisions of 40 C.F.R. Section 172.3(e), should Agency analyses justify such action. Depending on the Agency's evaluation of the risks, such action could be for particular nanopesticides, particular sub-classes of nanopesticides, or for the entire class of nanopesticides.

Other controls under FIFRA also exist for unregistered pesticides. For example, under FIFRA Section 3(a), EPA may through regulation limit the distribution, sale, and use of any unregistered pesticides undergoing R&D that are not the subject of an EUP or emergency exemption. In order to do so, however, EPA must demonstrate that such regulation is necessary to prevent unreasonable adverse effects on the environment.

C. Other Pre-Registration Exemptions Potentially Applicable to Nanopesticides

In addition to the general EUP exemptions, FIFRA Section 12(b)(5) also provides an exemption from civil penalties where an unregistered pesticide (such as an R&D nanopesticide) is being shipped for testing. Typically, the reasons involved with the testing include determining the potential value of the product as a pesticide or the product's toxicity or other properties. Although this exemption may be of concern to EPA for nanopesticides, this provision relates solely to shipment of R&D pesticides. Accordingly, any concerns that EPA may have with respect to appropriate labeling or use can be addressed through other FIFRA provisions as discussed in this paper.

D. Temporary Tolerance Level

Testing nanopesticides may result in nanopesticide residues on or in foods. In such situations, EPA may issue a temporary tolerance level for the expected nanopesticide residue prior to issuance of an EUP. The Agency would need to determine whether a temporary tolerance level would be required for nanopesticides under FIFRA Section 5(b), just as EPA would for any other R&D pesticide. With respect to application to nanopesticides, the terms of Section 5(b) do not appear otherwise to restrict EPA's regulatory authority in this regard simply because of the unique characteristics of nanopesticides. Accordingly, FIFRA appears to grant EPA wide latitude in this area.

In the case where a temporary tolerance already exists for the conventional version of a nanopesticide, EPA may wish to consider whether the Agency would need to revise the applicable tolerance, or issue a separate tolerance altogether, in order to address the nanopesticide version and the particular circumstances associated with that pesticide.

E. Studies

Under FIFRA Section 5(d), EPA may determine whether to require certain studies to be performed during the EUP period. Thus, EPA can sometimes require testing as a condition of granting an EUP. This provision, however, applies only to "a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide." Where a conventional registered pesticide contains the same "chemical or combination of chemicals" used in a nanopesticide, this provision apparently would not apply.

F. State Issuance of EUPs

Under FIFRA Section 5(f) and 40 C.F.R. Part 172, Subpart B, EPA has authorized states to issue EUPs under state authority. A number of states have applied for and received EPA authorization. Given the unique properties of nanopesticides and the authorization given to states to issue EUPs, EPA may wish to consider whether it should amend that authorization and its regulations in light of the unique characteristics of nanopesticides.

Regardless of whether EPA chooses to amend those regulations, the Agency still retains broad authority over state-issued EUPs under 40 C.F.R. Section 172.26. Specifically, those provisions require states issuing, amending, or revoking state-level EUPs to provide EPA with notification of such actions. EPA retains the ability to amend or revoke such EUPs provided sufficient justification. Accordingly, while EPA may wish to revisit whether the provisions of 40 C.F.R. Section 172.26 require revision in light of the unique properties of nanopesticides, existing regulatory authority already provides a significant degree of post-issuance oversight. Any subsequent changes deemed appropriate or necessary would likely be more effective prior to issuance by the authorized state.

III. EPA AUTHORITY TO REQUIRE REGISTRATION OF NANOPESTICIDES

A. The Registration Requirement Gives EPA Substantial Control over Nanopesticides

The centerpiece of EPA's FIFRA authority to regulate nanopesticides is the registration requirement of FIFRA Section 3. Subject to limited exceptions, no one may distribute or sell any unregistered pesticide, a prohibition backed up by strong enforcement tools. As part of the registration process, EPA can require applicants to develop extensive information relevant to an assessment of the pesticide's risks and benefits. Registration itself is not a simple up-or-down decision, but rather is always a limited approval that conditions the use of a pesticide in a manner designed to prevent unreasonable adverse effects. Thus, through the registration requirement, EPA may prohibit the use of nanopesticides presenting unreasonable adverse effects on human health or the environment, and may restrict other nanopesticides in a tailored manner so as to ensure that the risks do not become unreasonable.

If a nanopesticide is unregistered, it may not be distributed or sold in the United States (except under exceptions such as that for R&D discussed above and certain export exemptions).[11] Moreover, distribution and sale of a registered nanopesticide is also prohibited if the pesticide is distributed, sold, or used in a manner that departs from the conditions of EPA's approval, such as claims substantially different than those approved in a registration,[12] a composition different from that reviewed in the registration[13] or that is adulterated,[14] or a use

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11 FIFRA §§ 12(a)(1)(A), 17(a), 7 U.S.C. §§ 136j(a)(1)(A), 136o(a).

12 FIFRA § 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B).

13 FIFRA § 12(a)(1)(C), 7 U.S.C. § 136j(a)(1)(C).

inconsistent with the product's labeling.[15] Violation of these prohibitions can bring civil or criminal penalties under FIFRA Section 14, and orders for stop sale, removal, or seizure under FIFRA Section 13. EPA can suspend or cancel the registration or change its classification under FIFRA Section 6, and can order a recall under FIFRA Section 19(b). It can inspect for compliance under FIFRA Section 9. These enforcement tools give EPA authority to ensure that its ability to control nanopesticides through registration is effective.

Before exercising its enforcement authority against distributors and sellers of unregistered nanopesticides, EPA may want to educate them about the application of FIFRA to nanopesticides. As can be seen with some nanotechnology-based consumer products, non-traditional pesticide producers are entering the market. Due to the unique characteristics of nanopesticides, some producers and sellers may not recognize that FIFRA applies to their products and may be unaware of their obligations under FIFRA.

B. Whether Nanopesticides Are Covered by Existing Registrations of Conventional Pesticides

A threshold question is whether a nanopesticide is unregistered. This question arises where a conventional version of a nanopesticide is already registered. This question under FIFRA resembles that under TSCA as to whether a nanomaterial is an existing or new chemical substance, but the resolution under FIFRA is clearer than that under TSCA.

Under FIFRA Section 3(c)(5)(D), registration decisions depend in part upon an EPA determination that a pesticide "will not generally cause unreasonable adverse effects on the environment." Thus, EPA has both the authority and responsibility to determine whether the benefits of a nanopesticide outweigh its risks, and to determine the conditions under which a nanopesticide may be registered so as to limit those risks appropriately. Key factors in that determination are the claims and composition of the nanopesticide. Since the precise balancing of risks and benefits of a nanopesticide is likely to be different than that for a corresponding registered conventional pesticide, it is likely that EPA would take the position that use of nanoscale ingredients in place of conventional ingredients in a registered pesticide would necessitate the need for a new or amended registration.

In contrast, regulation under TSCA Section 5(a)(1) depends on whether a prospective PMN chemical has the same "particular molecular identity" as an existing chemical,[16] a determination that is independent of risk assessment considerations. Under TSCA the question turns on chemistry, which is not under EPA's control; but under FIFRA the question turns on risk assessment, which is under EPA's control.

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14 FIFRA § 12(a)(1)(E), 7 U.S.C. § 136j(a)(1)(E).

15 FIFRA § 12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G).

16 *See* TSCA § 3(2)(A)(i), 15 U.S.C. § 2602(2)(A)(i).

Under FIFRA, a pesticide is considered unregistered if its claims differ substantially from claims made for the registered pesticide, or if its composition differs from the composition of the registered pesticide.[17] On the other hand, a pesticide with the same formulation and claims as a registered pesticide may be added to the registration by supplemental statement (*i.e.*, without a separate risk assessment).[18]

The claims made for a nanopesticide may well differ from those made for a corresponding registered conventional pesticide, since nanotechnology allows for many new applications. Taking the antimicrobial active ingredient silver as an example, macro versions of silver-based pesticides are registered for use in swimming pools and other applications. Silver-based nanopesticides are being used as antimicrobials in fabrics, appliances, and other consumer applications.[19] Although both sets of uses involve antimicrobial activity, the details on the claims may well differ. Such differences may support an EPA determination that registrations for macro versions may not apply to nano versions.

Composition includes the identity of both active and inert ingredients and their ratios. Thus, the issue of whether or not a nanopesticide has the same composition as a corresponding registered conventional pesticide is not simply a function of whether the nano ingredient is an active or an inert. Given the unique characteristics of nanomaterials, it is unlikely that a nanopesticide will have the same composition as the corresponding registered macro version.

Even where the claims and composition of a nanopesticide are ostensibly identical to that of its macro version, EPA could take the position that the substitution of a nanoscale ingredient for its macro counterpart constitutes a change in composition *per se*. Moreover, the product chemistry, toxicology, and other information submitted for the macro version under 40 C.F.R. Part 158, Subparts C and D almost certainly would not apply to the nano version.

The unique characteristics of a nanopesticide will most likely result in different risks and benefits than its macro version. Thus, EPA's previous resolution of the balance of risks and benefits, and appropriate control measures, for the corresponding conventional pesticide is likely to differ from that for the nanopesticide, even where the composition and claims are ostensibly identical.

Thus, a new or amended registration application will be needed for a nanopesticide, at least in most cases. Where the registrant of a conventional pesticide applies for registration of a nano version of that pesticide, an application for an amended registration of the

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17 FIFRA § 12(a)(1)(B) and (C), 7 U.S.C. § 136j(a)(1)(B) and (C).

18 FIFRA § 3(c), 7 U.S.C. § 136a(c).

19 *See* Woodrow Wilson International Center for Scholars, Project on Emerging Technologies, Nanotechnology Consumer Products Inventory, available at http://www.nanotechproject.org/index.php?id=44.

corresponding macro pesticide under FIFRA Section 3(c)(7) and 40 C.F.R. Section 152.44 might be appropriate. An amended registration application could be required to provide additional information specific to the nanopesticide's risks and benefits.

C. Data Requirements for Registration of Nanopesticides

To perform the statutorily-mandated risk assessment for a nanopesticide, EPA needs information on the potential risks and benefits of the nanopesticide. Under FIFRA Section 3, EPA may obtain the necessary data from prospective registrants. This authority contrasts with EPA's inability to require testing of PMN chemicals except through a consent order under TSCA Section 5(e). Risk assessments under TSCA Section 5(a)(1) necessarily rely on structure-activity relationships and other assumptions in many instances, which may create difficulties for EPA where the unique characteristics of nanomaterials make analogies to conventional chemical substances unreliable. Under FIFRA, however, EPA can ensure that the Agency has all the data on the specific nanopesticide necessary to perform its risk assessment.

Under FIFRA Section 3(c)(2)(A), EPA may publish guidelines for the kinds of information that it needs to support registration, and it may revise those guidelines from time to time. EPA's current data requirements appear in 40 C.F.R. Part 158. EPA could develop data requirements specifically for nanopesticides. It has done so for genetically modified biochemical pesticides and microbial pesticides.[20] To date, EPA has not promulgated data requirements specifically for plant-incorporated protectants,[21] although it is considering doing so.[22] EPA may wish to consider whether adopting data requirements specifically for nanopesticides would be helpful for the Agency in conducting its risk assessments.[23]

For example, EPA's current data requirements for physical and chemical characteristics (color, melting point, vapor pressure, etc.) do not address the key characteristics that denote the unique character of nanomaterials.[24] Also, since nanomaterials may be used in

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20 40 C.F.R. §§ 158.690, 158.740.

21 *See* 40 C.F.R. Part 174, Subpart H (data requirements for plant-incorporated protectants -- reserved).

22 EPA has indicated that it intends to propose data requirements for the registration of plant-incorporated protectants in February 2007. 71 Fed. Reg. 23226, 23327 (Apr. 24, 2006) (semiannual regulatory agenda).

23 EPA has recently proposed updates to its data requirements for biochemical and microbial pesticides, 71 Fed. Reg. 12071 (Mar. 8, 2006), and for conventional pesticides, 70 Fed. Reg. 12276 (Mar. 11, 2005).

24 40 C.F.R. § 158.190.

nanopesticides at extremely low levels, current thresholds and exemptions may not be appropriate.[25] EPA may also want to revisit testing guidelines for application to nanopesticides.

D. Registration Decisions for Nanopesticides

Where a candidate nanopesticide presents some data gaps (which appears likely for most nanopesticides, at least for the near term), EPA has discretion to review the nanopesticide registration application under criteria which allow for the conditional registration of the pesticide, pending the development of additional required data, under FIFRA Section 3(c)(7).[26]

In addition, when making registration decisions, EPA may impose appropriate restrictions on the registration of a nanopesticide in order to prevent it from causing unreasonable adverse effects. Among the restrictions available to EPA for nanopesticide registrations in appropriate cases are the following:

- Registration for general use or restricted use under FIFRA Section 3(d) and 40 C.F.R. Part 152, Subpart I.
- Labeling restrictions under FIFRA Section 3(c)(5)(B) and 40 C.F.R. Part 156. These may include use of personal protective equipment, disposal restrictions, use restrictions, etc.
- Tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408 and 40 C.F.R. Part 180.
- Worker protection standards under FIFRA Section 25(a) and 40 C.F.R. Part 170.
- Packaging standards under FIFRA Section 25(c)(3) and 40 C.F.R. Part 157.

As appropriate, EPA may want to revise its implementing regulations for these provisions to address the unique circumstances of nanopesticides.

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25 *See. e.g.*, 40 C.F.R. § 158.155(c) (0.1% threshold for impurities); 40 C.F.R. § 155(e) (no information required for impurities associated with inerts, even inerts which may be nanoparticles); 40 C.F.R. § 158.175(b)(2) (table of standard certified limits); Pesticide Registration (PR) Notice 96-8, "Toxicologically Significant Levels of Pesticide Active Ingredients" (Oct. 31, 1996), § IV (guidance on levels considered toxicologically significant), available at http://www.epa.gov/opppmsd1/PR_Notices/pr96-8.html.

26 *See* 40 C.F.R. § 152.111.

IV. EPA'S POST-REGISTRATION AUTHORITY TO REGULATE NANOPESTICIDES

Nanotechnology is both new and rapidly developing. EPA may anticipate that significant information relevant to nanopesticides will continue to become available for years. As EPA approves registrations for nanopesticides, it may do so with the assurance that it has substantial authority under FIFRA to amend its regulation of those nanopesticides even after granting registration.

EPA can expect to receive relevant information directly from nanopesticide registrants. FIFRA Section 6(a)(2) imposes on each registrant of a nanopesticide the obligation to notify EPA promptly of "additional factual information regarding unreasonable adverse effects on the environment of the pesticide." EPA regulations under 40 C.F.R. Part 159 specify particular kinds of information required to be submitted. The information may relate to a class of registered pesticides, rather than to a particular pesticide.[27] In addition, there is a catch-all provision for information that the registrant knows or should know that EPA might regard as raising concerns about the continued registration of the pesticide or about the terms and conditions of that registration.[28] This threshold for reporting is arguably lesser than, or at least comparable to, the "substantial risk" criterion for reporting of information under TSCA Section 8(e).

EPA may also exercise other post-registration authority. For example, EPA chose to develop a tailored requirement for reporting post-registration information for plant-incorporated protectants.[29] EPA also has issued a reminder to registrants of genetically engineered microbial pesticides of the need to report adverse effects information under FIFRA Section 6(a)(2).[30] EPA may wish to undertake similar action for nanopesticides as well.

EPA can also require nanopesticide registrants to develop new data post-registration. FIFRA Section 3(c)(2)(B) authorizes EPA to require registrants to conduct new studies, and FIFRA Section 4(d)(3) allows EPA to require submission of missing or inadequate data in connection with reregistration. Section 3(c)(2)(B) can be triggered whenever EPA determines that such new data are "required to maintain in effect an existing registration of a pesticide." This is a lesser threshold than the thresholds under TSCA Section 4(a) for EPA to issue a test rule.

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27 *See* PR Notice 98-3, "Guidance on Final FIFRA Section 6(A)(2) Regulations for Pesticide Product Registrants" (Apr. 3, 1998), § X, available at http://www.epa.gov/opppmsd1/PR_Notices/pr98-3.pdf.

28 *See* 40 C.F.R. § 159.195(a).

29 *See* 40 C.F.R. § 174.71.

30 51 Fed. Reg. 23313, 23320 (June 26, 1986).

EPA must eventually reconsider its registration decisions in light of post-registration developments. Under FIFRA Section 3(g)(1)(A), EPA is required to review a pesticide's registration every 15 years. The 15-year review interval does not preclude any earlier review of the registration.[31] Reregistration is required under FIFRA Section 4(a) for pesticides containing active ingredients also contained in any pesticide initially registered before November 1, 1984. As EPA conducts its reregistration reviews, the Agency can consider the particular hazards presented by nano versions of those active ingredients. While reconsideration of a new registration of a nanopesticide will not occur for many years, EPA may grant initial registrations for nanopesticides knowing that reregistration will eventually be required. Reregistration decisions have a lower threshold for EPA action than does TSCA Section 6(a), with its requirement that EPA determine that a chemical substance or mixture "presents or will present an unreasonable risk of injury to health or the environment."

In appropriate cases, EPA may also act to protect the public from nanopesticides without waiting for reregistration. Based on sufficient evidence, under FIFRA Section 6, EPA may by order cancel or suspend a registration, or change its classification. Under FIFRA Section 13, EPA may issue stop sale, use, or removal orders for pesticides whose registrations have been cancelled or suspended. EPA may also order a recall under FIFRA Section 19(b) for such pesticides. Past experience demonstrates that EPA's recall authority has proven easier to use than its "imminent hazard" authority under TSCA Section 7.

CONCLUSION

The preceding discussion indicates that EPA can regulate nanopesticides adequately through its existing statutory authority, although it may want to revisit its current regulations and guidance to address the unique characteristics of nanopesticides.

Congress did provide additional statutory authority to regulate antimicrobials under the Food Quality Protection Act (FQPA), but that authority mostly addressed procedure rather than substantive criteria for registration.[32] The FQPA does not establish a precedent for EPA needing legislative action to address particular classes of pesticides presenting different characteristics than the pesticides traditionally addressed by FIFRA.

The better precedent is genetically engineered microorganisms used as pesticides. In 1986, EPA determined that it could regulate the pesticidal products of biotechnology through FIFRA, despite the Agency's recognition that at least some of those products were likely to exhibit new traits. EPA addressed such factors as EUP exemptions, data requirements for registration, and post-registration reporting of adverse effects information for bioengineered

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31 *See* FIFRA § 3(g)(1)(B), 7 U.S.C. § 136a(g)(1)(B).

32 Food Quality Protection Act of 1996, Pub. L. No. 104-170, Title II, Subpart B, amended by the Antimicrobial Regulation Technical Corrections Act of 1998, Pub. L. No. 105-324. *See* 64 Fed. Reg. 50672 (Sept. 17, 1999) (proposed rule to implement this aspect of the FQPA).

microbial pesticides under FIFRA without the need for new legislative authority.[33] More recently, in 2001 EPA promulgated regulations to address a particular class of bioengineered pesticides, plant-incorporated protectants, again without additional legislative authority.[34] These examples suggest that EPA can regulate nanopesticides effectively under FIFRA.

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33 *See* 51 Fed. Reg. at 23313.

34 66 Fed. Reg. 37772 (July 19, 2001) (40 C.F.R. Part 174). The passage of the FQPA in 1996 had an incidental impact on this rulemaking.