The small size of certain nanoparticles facilitates their biological uptake into cells.
manufacture, import, and processing of existing chemical substances for a use that the EPA determines to be a “significant new use.” New, but not existing, chemical substances are subject to the PMN requirement set forth in TSCA Section 5(a)(1)(A). Unless a PMN exemption applies, a company must submit a completed PMN form to the EPA at least ninety days before commencing the manufacture or import of any new chemical substance. Through the PMN review process, EPA assesses the new chemical and determines whether its manufacture, importation, processing, and/or distribution in commerce may present an unreasonable risk of injury to health or the environment.

Exemptions from the PMN process are either “self-executing” or require prior EPA approval. Self-executing exemptions are those that take effect once an entity determines that the exemption applies, and the company can manufacture the new chemical substance in the United States without the need for a PMN, provided that they comply with any recordkeeping or other applicable requirements for the particular exemption. Self-executing PMN exemptions include the exemption for chemical substances with no separate commercial purpose, the polymer exemption, and the research and development (“R&D”) exemption.

Other exemptions from the PMN requirement require prior EPA approval. In those situations, entities must submit, and EPA must approve, an exemption application before the entity can commence manufacture of the new chemical, subject to compliance with any recordkeeping or other applicable requirements. PMN exemptions that require prior EPA approval include the low volume exemption (“LVE”), the low release and low exposure exemption (“LoREX”), and the test marketing exemption (“TME”).

The PMN exemptions of greatest importance to the emerging nanotechnology industry include the LVE, the LoREX, and the R&D exemption, which appears to be uniquely well-suited for nanotechnology R&D undertaken by start-up companies, research laboratories, universities, and others. As noted above, the LVE and the LoREX require prior EPA review and approval.

The EPA bases eligibility for an LVE on the manufacture of a new chemical in quantities of 10,000 kilograms—approximately 22,000 pounds—or less per year, while it bases eligibility for a LoREX on meeting several regulatory criteria for release and exposure throughout the manufacture, processing, distribution, use, and disposal of the chemical. Once EPA notifies an applicant that it granted the LVE or LoREX application, or if the thirty-day review period expires without notice from EPA, manufacture or import of the chemical substance may commence, consistent with the terms of the exemption.

TSCA Section 5(e) authorizes EPA to issue administrative orders controlling new chemical substances when it finds, after review of a PMN, that insufficient information exists to permit a reasoned evaluation of the risk, and either the chemical may present an unreasonable risk to health or the environment, or it will be produced in substantial quantities that will enter the environment or to which there will be substantial or significant human exposure. In an order, the EPA may ban or limit the manufacture, processing, distribution, use, or disposal of the chemical. EPA must propose a Section 5(e) order prior to the expiration of the ninety-day PMN review period. As a matter of practice, rather than acting unilaterally under Section 5(e), EPA typically enters into a consent order with a PMN submitter, under which the latter agrees to restrict the manufacture, processing, distribution, use, or disposal of the new chemical substance pending the development of data necessary to evaluate the potential hazards.

**EPA’s “Significant New Use” Authority**

TSCA Section 5 authorizes EPA to review and assess the potential risks posed by significant new uses of existing chemical substances. A significant new use rule (“SNUR”) determines that a use is significant and new. A Significant New Use Notice (“SNUN”) is the form an entity must submit to EPA at least ninety days prior to any manufacture, import, or processing for that use. Some have suggested that the co-location of EPA’s SNUR authority and PMN requirement in the same statutory section is a clear indication that Congress intended EPA to regulate new chemicals and significant new uses of existing chemicals similarly. In fact, the TSCA legislative history reveals that EPA’s SNUR authority complements its PMN authority.

A key distinction between EPA’s PMN authority and its SNUR authority is that under the latter, EPA first must issue a SNUR, whereas with the former, both the statute and a generic implementing rule already mandate the submission of a PMN. Once EPA issues a SNUR, the two provisions operate in much the same way, and a SNUN is submitted on the same form and contains virtually the same information as a PMN.

In promulgating a SNUR, EPA must explain how it considered all relevant factors, including the following factors specifically mentioned in the statute: “the projected volume of manufacturing and processing . . . the extent to which a use changes the type or form of exposure to human beings or the environment . . . the extent to which a use increases the magnitude and duration of exposure of human beings or the environment . . . and . . . the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal.” EPA need not make a legal finding with respect to the potential harm that the existing chemical may pose, but rather, EPA need only consider the relevant factors.

Importantly for present purposes, EPA is authorized to issue SNURs for categories of chemical substances. The term “category of chemical substances” is defined as “a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in a mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of [TSCA].” Thus, the criteria for qualifying as a category are extremely broad.

**EPA’s Authority under TSCA Section 8**

TSCA Section 8 gives EPA broad information-gathering powers. These powers include the ability to impose recordkeep-
ing and reporting requirements for production, use, and exposure-related information under Section 8(a), and requirements for the submission of “health and safety study” data under Section 8(d). Pursuant to regulations issued by EPA under Section 8(c), manufacturers, importers, and processors of chemical substances must create and maintain records of allegations—whether written or oral—that a particular chemical “caused a significant adverse reaction to health or the environment.” A company must make its Section 8(c) records available for inspection by EPA at any time and submit them to EPA upon request.

Section 8(e), the self-executing “substantial risk” reporting provision of TSCA, obligates manufacturers, processors, and distributors as follows:

Any person who manufactures, processes, or distributes in commerce a chemical substance . . . and who obtains information which reasonably supports the conclusion that such substance . . . presents a substantial risk of injury to health or the environment shall immediately inform [EPA] of such information unless such person has actual knowledge that [EPA] has been adequately informed of such information.

This reporting requirement is important and may have special significance for companies working with ENM. Historically, penalties for non-compliance with the Section 8(e)’s substantial risk reporting obligation have been severe, and the EPA collected its largest civil administrative penalty ever from alleged Section 8(e) reporting violations.

**Applicability of TSCA to ENM**

Several of the key TSCA issues raised in connection with the application of TSCA to ENM include whether TSCA should regulate ENM consisting of Inventory-listed chemicals as “new chemical substances;” whether certain PMN exemptions are appropriate when applied to ENM; and whether TSCA’s information-gathering and reporting provisions are sufficiently robust to address issues arising in connection with ENM.

**ENM Consisting of Inventory-Listed Chemicals**

Several well-respected organizations, including Environmental Defense (“ED”) and the Natural Resources Defense Council (“NRDC”), have questioned whether TSCA is well-suited to manage potential EHS risks believed to be posed by ENM. These organizations have recommended that nanoscale versions of Inventory-listed chemicals be considered new chemical substances for purposes of TSCA Section 5. As stated by ED, “engineered nanomaterials are ‘new’ substances under TSCA (and thus subject to PMN review), even where a material has a chemical structure that is identical to a substance already included on the Inventory, unless the nanomaterial’s chemical and physical properties are demonstrably identical to an existing conventional substance with the same chemical structure.” In short, the argument is that because nanoscale versions of existing macro-scaled chemicals are designed to have novel and enhanced properties and/or characteristics that differ from the macro-sized counterparts, it is reasonable to conclude that the nanoscale versions may pose risks not associated with their conventional counterparts, such that the nanoscale versions should be considered new chemicals and thus subject to PMN review.

TSCA applies to ENM that meet the broad statutory definition of “chemical substance.” Conceding that ENM, which are chemical substances, are subject to TSCA, the issue really is which TSCA provisions apply. Proponents of the argument that nanoscale versions of existing chemicals should be regulated as new substances claim this interpretation of TSCA is good public policy and could prevent any unintended adverse human health and environmental consequences that may be associated with ENM. They also assert that ENM are of interest precisely because they are new and special. Because these materials are believed to offer new features and added value, they should be subject to TSCA’s new chemical review provisions.

A third argument offered is that the TSCA definition of “chemical substance” encompasses more than just a substance’s molecular structure. ED, for example, claims nothing in TSCA expressly precludes the definition of “chemical substance” from including physical and chemical properties.

The American Chemistry Council (“ACC”) Nanotechnology Panel, on the other hand, claims that nanoscale versions of Inventory-listed substances are not new chemical substances for TSCA purposes and cannot be considered new based on the very definition of “chemical substance.” A “chemical substance” is defined by its “particular molecular identity,” and the definition makes no mention of a substance’s physical and chemical properties. In ascertaining whether a particular substance appears on the Inventory, all that matters legally, according to the ACC Nanotechnology Panel, is whether, based on the substance’s molecular identity, it is or is not listed on the Inventory.

Additionally, the Panel claims that EPA’s historic course of conduct has been to consider only a chemical substance’s molecular identity, not its physical or chemical properties. This argument finds support in the ABA SEER Paper, which asserts “EPA’s emphasis on molecular structure is reflected in the PMN review process.” The ABA SEER Paper continues:

The initial steps of the PMN review process involve EPA establishing a complete and accurate chemical name for the substance and determining whether the chemical is already on the Inventory. If EPA determines, based on the chemical identity of the substance, that it is already on the Inventory, the PMN review ceases and the submitter is notified that the chemical can be manufactured in the U.S. This determination is made without any reference to the physical or chemical properties of the chemical.

The ABA SEER Paper acknowledges that the statutory term “particular molecular identity” is “sufficiently flexible as to take into account physical properties or other defining characteristics in addition to molecular structure, at least to a limited degree,” but it concludes “molecular structure is the definitive characteristic in most instances.”

Even if EPA announced that nanoscale versions of Inventory-listed chemicals are existing and not new chemicals for TSCA purposes (and as will be seen below, EPA is leaning...
strongly in this direction), EPA nonetheless has broad authority under TSCA to consider any potential risks posed by nanoscale substances. The ABA SEER Paper emphasizes that, beyond the PMN requirement, EPA has broad authority under other provisions of TSCA to address potential risks posed by ENM.66

Key among the other provisions is EPA’s SNUR authority. As indicated above, EPA can issue a SNUR, thereby triggering the need for companies to submit a SNUN.57 TSCA Sections 5(a)(1)(B) and 5(a)(2) thus enable EPA to perform the same risk assessment and implement the same risk management controls on existing chemical substances engineered at the nanoscale that can be applied to new chemical substances through the PMN process.58 SNUNs and PMNs use the same submission form, EPA Form 7710-25,59 and both notices “undergo the same review process.”60 Notably, EPA is authorized to issue a Section 5(e) (or Section 5(f)) order for any chemical substance “with respect to which notice is required by [Section 5(a)],” and that notice can be either a PMN under Section 5(a)(1)(A) or a SNUN under Section 5(a)(1)(B).61

In promulgating a SNUR, EPA must consider all relevant factors, including the four factors listed in the statute. Of the four statutory factors discussed above, the latter three appear to be especially relevant to ENM.62 EPA, however, is not restricted to the four statutory factors, and in fact “construes the statute to allow consideration of any other relevant factors.”63

The ABA SEER Paper also points out that EPA is not limited to issuing SNURs for individual ENM. Given the great diversity that reportedly characterizes these materials, EPA’s authority to issue a SNUR for a category or categories of existing ENM is important, particularly as the criteria for qualifying as a category are broad and may mean merely “in some . . . way suitable for classification as such for purposes of [TSCA].”64

**Appropriateness of Certain PMN Exemptions**

The appropriateness of several of the PMN exemptions is also debated. ED, for example, has urged the EPA “not to apply mass-based, or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials.”65 A key issue is the relevance of mass-based and volume-based criteria as applied to ENM, and whether these criteria could ever apply to ENM, which are in many cases unlikely to be produced in substantial quantities.

The appropriateness of the LVE in particular has been questioned on the grounds that the threshold level of 10,000 kilograms is too high, especially considering that few companies are expected in the near term to be producing ENM in amounts even approaching that level.66 At first glance, the suitability of this PMN exemption may seem questionable, but a closer review may suggest otherwise. Because the exemption requires prior EPA approval, EPA’s consideration of any potential risks posed by the ENM at issue can be expected to be comprehensive. In fact, EPA’s review of a PMN exemption for a carbon nanotube, originally submitted as a LVE, but later converted to a LoREX, took approximately one year and likely consumed considerable EPA resources and generated no small amount of deliberation and scrutiny.57

Although the LVE allows certain new chemicals, including those falling into the category of ENM, to avoid the full panoply of PMN review, this does not mean EPA does not consider carefully the EHS implications of the candidate substance. Indeed, the level of scrutiny the EPA reportedly devoted to the LVE/LoREX application likely exceeded the degree of scrutiny typically reserved for conventional new chemicals reviewed under the PMN program.

**EPA Nanotechnology Initiatives To Date**

EPA is to be commended for its leadership, vision, and energy in exploring early and creatively the application of TSCA to ENM. Two regulatory initiatives are worthy of discussion.

**TSCA PMN Decision Logic**—EPA’s Office of Pollution Prevention and Toxics (“OPPT”) developed a decision logic that its staff applies in assessing ENM submitted to EPA for PMN review under TSCA Section 5, or as part of PMN exemption applications. Use of the logic is resulting in EPA’s identifica-
tion of specific areas of inquiry unique to ENM. Primary among these areas are potential routes of exposure to workers and potential environmental releases. EPA is assessing the adequacy of personal protective equipment to prevent potential exposures to ENM during the manufacturing, processing, and/or distribution and use of these materials. EPA’s decision logic is believed to distinguish between true ENM, meaning those materials that meet the criteria set out by the NNI, and those materials that fall within the size range of 1-100 nanometers, but are not specifically engineered with the intent to enable novel, size-dependent properties. According to published sources, EPA has, as of August 2006, reviewed fifteen new chemicals that were deemed to fall within the nanoscale size range, one of which, a carbon nanotube, possessed properties deemed unique and resulted in EPA’s approval of a LoREX application in 2005.70

Now, the Inventory includes at least two new ENM. On June 9, 2006, and August 14, 2006, EPA issued Federal Register notices acknowledging the receipt of NOCs of siloxane-coated silica and siloxane-coated alumina nanoparticles.71

Nanoscale Materials Stewardship Program—In 2005, OPPT announced its interest in considering how best to obtain much-needed information on existing ENM, and convened a public meeting to discuss various options in June 2005.72 The discussion at the public meeting yielded a consensus that a voluntary program on existing ENM would have significant value. Shortly thereafter, EPA created an Interim Ad Hoc Work Group on Nanoscale Materials (“Work Group”) as part of the National Pollution Prevention and Toxics Advisory Committee (“NPPTAC”), a federal advisory group tasked with advising OPPT on TSCA and pollution prevention matters.73 On November 22, 2005, after the Work Group had met several times, NPPTAC submitted to the EPA Administrator its Overview Document on Nanoscale Materials, which outlined a framework for an EPA approach to a voluntary program for ENM and a complementary approach to new chemical nanoscale requirements under TSCA, and addressed various other issues pertinent to ENM.74

On October 18, 2006, EPA Assistant Administrator James Gulliford sent a letter to stakeholders formally announcing the development of the Nanoscale Materials Stewardship Program (“NMSP”) and inviting stakeholder participation in it.75 Several months later, EPA simultaneously published three Federal Register notices related to the NMSP.76 The first notice solicited public comment on EPA’s proposed Information Collection Request under the Paperwork Reduction Act, including a draft form that NMSP participants could use to submit data to EPA; the second announced a public meeting on the NMSP, and the third solicited public comment on two draft documents: the “Concept Paper for the Nanoscale Materials Stewardship Program under TSCA” (“NMSP Concept Paper”) and the “TSCA Inventory Status of Nanoscale Substances—General Approach” (“TSCA Inventory Paper”).77

The draft NMSP Concept Paper outlined EPA’s “initial thinking on the design and development” of the NMSP and explained that the program, in keeping with the Work Group’s recommendations, would consist of two parts, a “Basic Program” and an “In-Depth Program.”78 The draft TSCA Inventory Paper “inform[ed] the public of the approach EPA has historically taken under TSCA in evaluating whether chemical substances are new, and further inform[ed] the public of EPA’s intention to follow [the same] approach for nanomaterials that are chemical substances.”79 In the draft TSCA Inventory Paper, EPA explained that if a particular ENM has the same molecular identity as a non-nanoscale (i.e., macro) substance that is listed on the TSCA Inventory, then the ENM is an existing chemical irrespective of its particle size and physical/chemical properties.80 Thus, the TSCA Inventory Paper runs counter to the view expressed by ED, NRDC, and others, that nanoscale versions of Inventory-listed chemicals should be deemed new for purposes of TSCA Section 5.

The comment period for the NMSP documents closed on September 10, 2007, and EPA is now reviewing the various comments submitted.81 It is clear that EPA intends to proceed with the NMSP, and EPA hopes to launch the program by the end of 2007. EPA has indicated that regulatory efforts under TSCA are unlikely to happen until after the NMSP is well underway, but a TSCA Section 8(a) information-gathering rule is possible, and perhaps even likely.

CONCLUSION

The debate over TSCA’s application to ENM will continue for some time. The discussion above demonstrates that EPA has broad authority under TSCA, and that new legislation intended to address any potential risks that ENM might pose is unnecessary. EPA can review ENM under TSCA, either as new chemicals or as significant new uses of existing chemicals. EPA can conduct a comprehensive review of the exemptions from the PMN requirement. EPA can also collect information on and compel and enforce reporting obligations with respect to ENM.

EPA’s stated commitment to issue final guidance on these issues will greatly assist the regulated community in understanding EPA’s expectations regarding the submission of PMN and exemption applications for ENM and thus better prepare industry to undertake its TSCA compliance obligations consistently. In the interim, chemical manufacturers would be wise to consider carefully their TSCA compliance obligations, obtain legal advice when necessary, and seek EPA’s thoughts early and often regarding the regulatory status of ENM believed to consist of Inventory-listed substances.

Endnotes: TSCA and Engineered Nanoscale Substances continued on page 82
ENDNOTES: THE STATES AND THE WORLD continued from page 30

12 Hearing before the U.S. Sen. Committee on Public Works, 109th Cong. (Aug. 2, 2006) (testimony of William Rawson) (“TSCA is a well-crafted statute that has stood the test of time quite well.”)
13 Ernie Rosenberg, Presentation at the Bureau of National Affairs Teleconference: State Toxics Controls Programs: Reaching Beyond TSCA (Dec. 18, 2006).
17 NCEL, id. (showing that in 2007 legislation to restrict deca-BDE was introduced in California, Connecticut, Hawaii, Illinois, Michigan, Minnesota, Montana, and New York).
18 The Safer Alternatives Bill (H. 783/S. 558) focuses initially on ten chemicals or groups: lead, formaldehyde, trichloroethylene (TCE), perchloroethylene (“perc”), dioxins and furans, hexavalent chromium, organophosphate pesticides, 2,4-D herbicide, polybrominated diphenyl ethers (PBDEs), and diethylhexylphthalate (DEHP).
22 Memorandum from Linda Adams, supra id.
29 Mark Schapiro, Exposed: The Toxic Chemistry of Everyday Products and What’s At Stake for American Power (Chelsea Green Publishing 2007).
35 Louisville Charter, supra note 32.

ENDNOTES: TSCA AND ENGINEERED NANOSCALE SUBSTANCES continued from page 35

1 An earlier version of this Article was published in Nanotechnology Law & Business, Vol. 4 No. 1 (Mar. 2007).
15 15 U.S.C. § 2604(a)(1)(A); see, e.g., 40 C.F.R. §§ 720, 723 (containing EPA’s PMN regulations and several exemptions).

Id.


See S. Rep. No. 94-698, at 19 (1976) (“If a new use of an existing substance has been specified by the Administrator in accordance with this subsection [Section 5(a)(2)], all of the premarket notification procedures and authority during the premarket notification period apply to such new use of an existing substance.”)

See 40 C.F.R. § 720.22.


22 40 C.F.R. § 717.3(a).

23 40 C.F.R. § 717.17(a)-(b).


28 See id.

29 See id. at 3-4.


31 See generally 40 C.F.R. § 710.3.

32 See TSCA Inventory Nomenclature for Enzymes and Proteins, 69 Fed. Reg. 65565, 65567 (Nov. 15, 2004) (stating “the only way to determine if a substance is new or existing is by consulting the TSCA Inventory”).

33 ABA SEER Paper, supra note 33, at 8.

34 ABA SEER Paper, supra note 33, at 8.

35 ABA SEER Paper, supra note 33, at 9.


39 See 40 C.F.R. §§ 720.40(a)(2)/721.25(a) (regulating PMN and SNUN).

40 EPA AUTHORIES UNDER TSCA, supra note 37, at 12.


46 ED Letter, supra note 46, at 4-4.


49 To date, EPA has received at least one Section 8(e) submission (SEHQ-0403-15319 (Apr. 10, 2003)) addressing an engineered nanoscale material, although it is not clear from the submission whether the nanoscale material was existing or new. See generally OPPT Accomplishments Report, New Nanotechnology Products available at http://www.epa.gov/oppt/ar/20052006/managing/new_nano.htm (last visited Nov. 1, 2007).


54 Id.

55 Letter from James B. Gulliford, Assistant Administrator for Prevention, Pesticides & Toxic Substances, to Stakeholders (Oct. 18, 2006) (laying out EPA’s goal “to implement TSCA in a way that enables responsible development of nanotechnology and realizes its potential environmental benefits, while applying sound science to assess and, where appropriate, manage potential risks to human health and the environment presented by nanoscale materials”), available at http://www.epa.gov/opptintr/nano/nmsrfr.htm (last visited Oct. 14, 2007).


ENOTE:

ENDNOTES: ENVIRONMENTAL STANDARDS IN U.S. FREE TRADE AGREEMENTS continued from page 36

3 Bayview, id.

ENDNOTES: MINNEAPOLIS BRIDGE COLLAPSE continued from page 37

3 I-35W Bridge Collapse, supra note 1.
7 Hunt, supra note 5, at 8.

ENDNOTES: A ROAD MAP TO A BETTER NEPA continued from page 43

10 40 C.F.R. § 1500.1(b).
13 40 C.F.R. § 1502.22.
14 The scope of an EIS is relatively wide and requires the agency to “discuss the purpose and need for the proposed action, environmental impacts resulting from the actions, unavoidable adverse environmental impacts, alternatives to the proposed action, the relationship between short-term uses and long-term productivity, and the amount of resources that must be devoted to the proposed action.” Citizens’ Comm. to Save Our Canyons v. U.S. Forest Serv., 297 F.3d 1012, 1022 (10th Cir. 2002); 42 U.S.C. §4332(2)(C)(i)-(v); 40 C.F.R. § 1502.10.
15 COUNCIL ON ENVIRONMENTAL QUALITY, supra note 5.
17 40 C.F.R. § 1508.8.
18 40 C.F.R. § 1508.7.
19 Neighbors of Cuddy Mountain v. U.S. Forest Serv., 137 F.3d 1372, 1379-80 (9th Cir. 1998).
20 See Ocean Advocates v. U.S. Army Corps of Eng’rs, 361 F.3d 1108, 1129 (9th Cir. 2004); Muckleshoot Indian Tribe v. U.S. Forest Serv., 177 F.3d 800, 811 (9th Cir. 1999) (holding that the cumulative impact statements that are provided in the EIS are far too general and one-sided to meet the NEPA requirements); see also High Sierra Hikers Ass’n v. Blackwell, 390 F.3d 630, 645-46 (9th Cir. 2004); Klamath-Siskiyou Wildlands Ctr. v. Bureau of Land Mgmt., 387 F.3d 899, 991-92 (9th Cir. 2004) (asserting that the analyses performed by the BLM do not sufficiently consider the cumulative impacts posed by the timber sales); Wyoming Outdoor Council Powder River Basin Res. Council v. United States, 351 F. Supp. 2d 1232, 1238 (D. Wyo. 2005); Defenders of Wildlife v. Ballard, 73 F. Supp. 2d 1094, 1114 (D. Ariz. 1999).
21 See Kleppe v. Sierra Club, 427 U.S. 390, 410 (1976); Northcoast Envtl. Ctr. v. Glickman, 136 F.3d 660, 688 (9th Cir. 1998). (holding that the preparation of a programmatic EIS, will permit agency to assess the environmental consequences of “an entire policy initiative rather than performing a piecemeal analysis”).
22 Bartell, supra note 4, at 848.
23 Bartell, supra note 4, at 848.
24 James L. Connaughton, Modernizing the National Environmental Policy Act: Back to the Future, 12 N.Y.U. ENVTL. L.J. 1, 9 (2003) (writing about the possibilities of using ERAs to improve the NEPA process, and saying, “[t]he question we must find an answer to now is how to pull environmental and risk assessments together in such a way to create a more programmatic view of planning and development”).
25 Bartell, supra note 4, at 848.
26 40 C.F.R. § 1502.22.
27 Seattle Audubon Soc’y v. Espy, 998 F.2d 699, 704 (9th Cir. 1993).
28 Seattle Audubon Soc’y, id.; see also Ecology Ctr., Inc. v. Austin, 430 F.3d 1057, 1065 (9th Cir. 2005).