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VIEWS OF THE AMERICAN CHEMISTRY COUNCIL NANOTECHNOLOGY PANEL ON THE BROAD SCOPE OF EPA'S AUTHORITY UNDER TSCA TO ADDRESS ANY POTENTIAL RISKS FROM ENGINEERED NANOSCALE MATERIALS

In the recent past, questions have arisen regarding the adequacy of current statutory and regulatory authorities to address potential risks that may arise from engineered nanoscale materials consisting of chemical substances. The American Chemistry Council Nanotechnology Panel (Panel) believes that authorities now available to the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) are sufficiently robust and flexible to address any such risk, and that additional legislation intended to address any potential risk that existing or new engineered nanoscale materials may pose is neither necessary nor advisable.

In this regard, the Panel understands that EPA is now considering the regulatory status under TSCA of existing nanoscale materials that consist of chemical substances listed on the TSCA Chemical Substance Inventory. Some have urged EPA to interpret TSCA to regulate such existing engineered nanoscale materials as though these substances were "new" chemical substances. This document, which is offered to assist EPA in its consideration of this topic, sets forth the well-supported legal basis for the position that engineered nanoscale materials consisting of existing chemical substances cannot properly be considered "new" chemical substances under TSCA, and further explains the basis for the Panel's view that TSCA as written and EPA's regulatory framework implementing TSCA's existing statutory provisions, are adequate and well-suited to address any potential human health and/or environmental risk that existing or new engineered nanoscale materials may be found to pose.

EXECUTIVE SUMMARY

As explained below, TSCA Section 3(2) defines a "chemical substance" solely by its "molecular identity." It makes no mention of a substance's physical and chemical properties. Congress left no doubt that whether a chemical is "new" (and thus subject to the premanufacture notification (PMN) requirements in TSCA Section 5) or existing (and thus not subject to TSCA PMN provisions) turns exclusively on the inclusion or non-inclusion of the substance's "particular molecular identity" on the TSCA Inventory. EPA's implementation of TSCA over the years evidences EPA's clear and consistent practice of identifying a chemical's identity only by its molecular formula and chemical structure. In the case of an existing nanoscale substance, precisely because it has a molecular identity -- a molecular formula and chemical structure -- that is identical to a chemical already on the TSCA Inventory, the nanomaterial, irrespective of its physical and chemical properties, constitutes an existing chemical substance under TSCA.

While the definition of "chemical substance" is central to the issue of whether a material is considered new or existing under TSCA, equally important is the scope of EPA's authority under TSCA to address potential risks posed by chemical substances, whether new or existing. Review of TSCA will confirm that Congress gave EPA authority to require premarket approval of new chemical substances and a robust set of statutory provisions to address potential risks determined to arise from the manufacture, processing, distribution in commerce, use and/or disposal of existing chemical substances. EPA's implementation of provisions pertinent to existing chemical substances over the last several decades has evidenced EPA's ability to abate risks comprehensively through many legal options, as Congress envisioned EPA would when enacting TSCA. To those who assert these provisions are inadequate or ill-suited to address risks

that have not yet been and may never be identified with respect to existing engineered nanoscale materials, the Panel respectfully disagrees, for the reasons set forth below.

This paper is in two parts. Part I sets forth the statutory definition and history of the term "chemical substance" within the broad context of Congress's underlying intent in distinguishing between "new" and existing chemical substances for TSCA purposes. Part II provides a broad overview of the authorities and tools under TSCA available to EPA to address potential risks from existing substances. Review of these provisions demonstrates that EPA has ample authority to address any potential risk that engineered nanoscale materials may pose.

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PART I

I. THE TSCA DEFINITION OF "CHEMICAL SUBSTANCE" IS CENTRAL TO DETERMINING WHETHER A CHEMICAL SUBSTANCE IS NEW OR EXISTING

A. The Statute

TSCA Section 3(2) defines the term "chemical substance" in pertinent part as follows:

> (A) Except as provided in subparagraph (B), the term 'chemical substance' means any organic or inorganic substance of a particular molecular identity, including
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> (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
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> (ii) any element or uncombined radical.[1]

A "new chemical substance" is defined as "any chemical substance which is not included in the chemical substance list compiled and published under section [8(b)] of [TSCA]."[2]

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[1] TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A); *see also* 40 C.F.R. §§ 710.3(d), 720.3(e). Subparagraph (B) expressly excludes the following from the definition of "chemical substance": mixtures; pesticides; tobacco and tobacco products; certain nuclear materials; firearms and ammunition; and food, food additives, drugs, cosmetics, and devices. TSCA § 3(2)(B), 15 U.S.C. § 2602(2)(B); *see also* 40 C.F.R. §§ 710.3(d), 720.3(e). With the exception of mixtures, all of these categories are regulated under other federal laws.

[2] TSCA § 3(9), 15 U.S.C. § 2602(9). TSCA Section 8(b)(1) requires EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or

The introductory language in Section 3(2)(A) emanates from the TSCA legislation first proposed by EPA in February 1971, "The Toxic Substances Control Act of 1971," which would have amended the Federal Hazardous Substances Act.[3] That proposed legislation, in turn, grew out of a Council on Environmental Quality (CEQ) report on perceived "problems associated with toxic substances in the environment" that found, *inter alia*, that existing legal authorities were "inadequate to control the actual and potential dangers of toxic substances comprehensively or systematically."[4]

Congressional efforts to enact TSCA spanned a six-year period, from 1971 through 1976, and the PMN requirements now found in TSCA Section 5 were a central part of the legislative debate.[5] While Congress did not expound on why it defined the term "chemical substance" in the manner that it did, Congress left no doubt about the scheme that was created: all "chemical substances" are either "new" or existing, and the "new" or existing determination hinges solely on the inclusion or non-inclusion of a "chemical substance" (*i.e.*, "a particular molecular identity") on the TSCA Inventory. "New chemical substances" are subject to the

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processed in the United States." TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1). That list of existing chemical substances is known as the TSCA Inventory.

3 *See* S. Rep. No. 92-783, at 17 (1972).

4 CEQ, *Toxic Substances* (Apr. 1971), at iv, 20, *reproduced in* Library of Congress, *Legislative History of the Toxic Substances Control Act Together With A Section-By-Section Index (1976)*, at 759, 783 (*TSCA Legislative History*).

5 *See generally* EPA, *Chemistry Assistance Manual for Premanufacture Notification Submitters* (Mar. 1997), at 106-07 (*Chemistry Assistance Manual*), available at http://www.epa.gov/opptintr/newchems/pubs/chem-pmn/index.htm.

PMN provisions in Section 5. As Senator Magnuson, one of the leaders of the Senate effort to enact TSCA, remarked during the Senate's consideration and passage of the TSCA Conference Report, "[d]eterminations of what is or is not a new chemical substance is [sic] made through the establishment of an inventory of chemical substances under section 8(b). If a substance does not appear on the inventory, then it must go through premarket notification 90 days prior to first manufacture."[6] As noted above, the Inventory mandated by TSCA Section 8(b) is "a list of each chemical substance which is manufactured or processed in the United States."[7]

The statutory definition of "chemical substance" is clear in two important respects: a "chemical substance" is defined solely by its "molecular identity"; and the definition makes no mention of a substance's physical and chemical properties. As the Supreme Court has stated, Congress must be presumed to have "[said] in [TSCA Section 3(2)(A)] what it mean[t] and mean[t] in [that provision] what it [said] there," *i.e.*, "molecular identity" is what sets one chemical substance apart from another.[8] Moreover, *expressio unius est exclusio alterius*: the

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6 *TSCA Legislative History* at 723; *see also* S. Rep. No. 94-698 at 22 (1976), *reproduced in TSCA Legislative History* at 178 (stating that "[t]o determine which substances are new chemical substances for the purpose of the [PMN] provisions of section 5, [section 8(b)] requires [EPA] to publish an inventory of existing chemical substances . . . . Substances not appearing on that inventory will be considered new chemical substances for the purposes of section 5"); H.R. Rep. No. 94-1341, at 43 (1976), *reproduced in TSCA Legislative History* at 450 (stating that "[t]he inventory is to be used by manufacturers and processors to determine if a chemical substance is a 'new' substance subject to the [PMN] requirements of section 5").

7 TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).

8 *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). As the Court went on to say in *Germain*, "[w]hen the words of a statute are unambiguous, then, this first canon [of statutory construction] is also the last: 'judicial inquiry is complete.'" *Id.* at 255 (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)).

express mention in Section 3(2)(A) of one determining criterion -- "molecular identity" -- implies the exclusion of another -- physical and chemical properties.[9] Indeed, in a House Foreign and Interstate Commerce Committee Report on the EPA-proposed TSCA legislation that passed the full House in 1972, which defined "chemical substance" in a virtually identical manner to TSCA Section 3(2), the Committee observed that "[t]he definition [of 'chemical substance'] is specifically limited to substances of a particular molecular identity, and in using the word 'element' the committee means the customary definition of a chemical element."[10]

EPA does not have discretion under Section 3(2) to interpret the phrase "particular molecular identity" so that it encompasses a substance's physical and chemical properties, thereby allowing a substance with a molecular formula and chemical structure already listed on the TSCA Inventory to be treated as a new chemical substance if it has novel physical and chemical properties. During the course of the legislative effort to enact TSCA, EPA expressed to Congress its desire to have some discretion under the Section 3(2) definition.[11]

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9 *See, e.g., Independent Ins. Agents of America, Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995).

10 H.R. Rep. No. 92-1477, at 5 (1972). The reported legislation, S. 1478, defined "chemical substance" to mean "any organic or inorganic substance of a particular molecular identity, or any uncombined chemical radical or element."

11 EPA proposed to both the Senate and House "that the definition of 'chemical substance' be amended to provide [EPA] with some flexibility to exclude in appropriate situations, certain substances from the definitions and thus from the requirements of the act or from particular provisions of the act," and explained that it "would exercise [its] discretion to exclude from the definition of chemical substances most substances manufactured in less than commercial quantities for the purpose of testing." S. Rep. No. 94-698, at 74, *reproduced in TSCA Legislative History* at 190; H.R. Rep. No. 94-1341, at 67, *reproduced in TSCA Legislative History* at 474.

While Congress ultimately included the various PMN exemption provisions in TSCA Section 5(h) and made its intent clear, through TSCA Section 5(i), that certain products (*e.g.*, incidental reaction products and byproducts) were not to be subject to the PMN requirements or included on the Inventory,[12] the clear, unequivocal statutory language in Section 3(2) demonstrates that Congress did not provide EPA with any discretion regarding the definition of "chemical substance."

With respect to the Section 3(2) definition, the TSCA Conference Report specifically states as follows:

> The conferees recognize that virtually no chemical substance exists in a completely pure state and intend that any reference to a chemical substance includes all impurities and concomitant products, including incidental reaction products, contaminants, co-products, and trace materials. Thus the definition of [the] term 'chemical substance' shall be applied to chemical substances as actually produced and marketed. For example, when [EPA] promulgates a rule under section 6(a) to regulate a particular substance, such rule will apply to the identified substance,

[12] *See* S. Rep. No. 94-698, at 19, *reproduced in TSCA Legislative History* at 175 (discussing substances that "would not be covered under the [PMN] provisions because they are not manufactured for a commercial purpose, *per se*"); H.R. Rep. No. 94-1341, at 13, *reproduced in TSCA Legislative History* at 421 (a substance "not to be used as a chemical substance, per se" is "not to be subject to the [PMN] requirements of section 5 even though the chemical substance resulting from such activity is not included on the inventory compiled under section 8(b)"); *id.* at 31, *reproduced in TSCA Legislative History* at 438 (if "what would technically be considered a 'new' chemical substance . . . is not manufactured for commercial purposes per se, it would not be subject to the [PMN] provisions"). TSCA Section 5(i) provides that "[f]or purposes of [Section 5], the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes." TSCA § 5(i), 15 U.S.C. § 2604(i). EPA abided by Congress's intent when it promulgated the provisions in 40 C.F.R. Sections 710.4(d)(1)-(8). *See* 42 Fed. Reg. 64572, 64585, 64587 (Dec. 23, 1977); 42 Fed. Reg. 39182, 39186 (Aug. 2, 1977).

> including all the impurities and other concomitant products, without explicitly identifying such impurities and concomitant products within the rule.
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> It is expected that [EPA] will develop guidelines for the purpose of clarifying the extent to which impurities and concomitant products will be included within a reference to 'chemical substance' as it relates to the various provisions of the Act. While impurities and concomitant products are included within references to a 'chemical substance' under the Act, [EPA] is obviously authorized to move against them separately under the applicable provisions of the Act.[13]

This excerpt is significant insofar as it establishes vis-à-vis impurities and concomitant products that EPA has discretion under TSCA, but not pursuant to Section 3(2) of the statute. Instead, Congress directed that for purposes of Section 3(2), impurities and concomitant products -- themselves "chemical substances" that can be regulated separately by EPA -- are deemed included within the "chemical substances" of which they are a part. EPA thus has discretion, but only to decide whether, and if so how, to regulate impurities separately under TSCA non-definitional sections.[14]

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[13] H.R. Conf. Rep. No. 94-1679, at 57, *reproduced in TSCA Legislative History* at 670.

[14] EPA's position under Sections 8(b) and 5 has always been that an "impurity," defined as "a chemical substance which is unintentionally present with another chemical substance," is neither included on the Inventory nor subject to PMN requirements because it is not manufactured or processed for distribution in commerce as a chemical substance *per se* and has no commercial purpose separate from the substance of which it may be a part. *See* 40 C.F.R. §§ 710.3, 710.4(d)(1), 720.3(m), 720.30(h)(1). Moreover, for purposes of the Inventory, EPA does not "distinguish among chemical substances which are identical except with respect to their impurities." 42 Fed. Reg. at 64588. In other words, "impurities are not included in the chemical identification for the Inventory listing of a chemical substance," meaning that "chemical substances which are identical except with respect to their impurities" have only one Inventory listing. EPA, *Questions & Answers for the New Chemicals Program (Q&A)*, at 2-1 (undated draft) (*Q&A Manual*), available at http://www.epa.gov/opptintr/newchems/pubs/qanda-newchems.pdf.

More importantly, in explicitly stating that the definition of "chemical substance" "shall be applied to chemical substances as actually produced and marketed," the Conference Report reflects the fact, just as the statute does in Sections 2(a)(2) and 5(h)(3), that chemical production methods were not, are not, and never will be static.[15] As with any industry, innovations are being constantly made in the chemical industry, and it is precisely such innovations that have led to existing nanoscale materials -- nanometer-sized particles of existing chemical substances. Just as Congress intended that any reference to a "chemical substance" includes all impurities and concomitant products, ostensibly it also intended that any such reference encompasses all particle sizes of the substance. As a result, a "chemical substance" listed on the TSCA Inventory encompasses an existing nanomaterial manufactured from that substance.

[15] Section 2(a)(2) contains the Congressional finding that "among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment," TSCA § 2(a)(2), 15 U.S.C. § 2601(a)(2), while Section 5(h)(3) contains the research and development exemption to the PMN requirements. TSCA § 5(h)(3), 15 U.S.C. § 2604(h)(3).

B. EPA Implementation of "Particular Molecular Identity" under TSCA Sections 5(d)(1) and 8(a)

EPA has consistently drawn the meaning of the phrase "particular molecular identity" from Sections 5(d)(1) and 8(a) of TSCA. Section 5(d)(1), which specifies the contents of a PMN, requires a manufacturer or importer to report, *inter alia*, certain information described in TSCA Section 8(a)(2).[16] Subsection (A) of Section 8(a)(2), in turn, explicitly mentions "the chemical identity, and the molecular structure of [a] chemical substance."[17]

In regulations issued by EPA pursuant to its authority under TSCA Section 8(a), EPA has stated that "chemical identity" refers to the Chemical Abstracts Service Registry Number (CASRN) of a chemical substance.[18] Under the original TSCA Inventory reporting regulations promulgated by EPA in 1977, the reporting form for chemicals with no known CASRN, EPA Form 7710-3C, requested "structural information, molecular formula, and other supplemental information to aid in the specific identification of the chemical substance."[19] Under the PMN regulations issued pursuant to TSCA Section 5, the "specific chemical identity"

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16 TSCA § 5(d)(1), 15 U.S.C. § 2604(d)(1).

17 TSCA § 8(a)(2)(A), 15 U.S.C. § 2607(a)(2)(A).

18 *See, e.g.*, 40 C.F.R. §§ 710.52(c)(3)(i), 712.28(a) (referencing EPA Form 7710-35); EPA, "Form U: Partial Updating of TSCA Inventory Data Base -- Production and Site Report" (EPA Form 7740-8, a/k/a/ Form U), available at http://www.epa.gov/opptintr/iur/iur02/pformu02.pdf; EPA, "Manufacturer's Report -- Preliminary Assessment Information," at Section II (EPA Form 7710-35), available at http://www.epa.gov/opptintr/chemtest/pubs/pairform.pdf.

19 42 Fed. Reg. at 64595.

of a new chemical substance includes the Chemical Abstracts (CA) Name (either a CA Index Name or a CA Preferred Name) based on the Ninth Collective Index of CA nomenclature rules and conventions, the CASRN if it already exists, and for Class 1 substances (*i.e.*, substances "having a chemical composition that can be represented by a specific, complete chemical structure diagram"), the molecular formula and chemical structure.[20] For Class 2 substances (*i.e.*, substances "that cannot be fully represented by a complete, specific chemical structure diagram"), in addition to the CA Name and the CASRN if one already exists, a PMN "must identify the immediate chemical precursors and reactants by specific chemical name and [CASRN], if the number is available" and also include "a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained."[21]

EPA has stated that chemical structure determines whether a chemical substance is a Class 1 or a Class 2 substance:

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[20] 40 C.F.R. §§ 720.25(b), 720.45(a)(1); *see also* EPA, "Premanufacture Notice," at Section I.B.1 (EPA Form 7710-25), available at http://www.epa.gov/opptintr/newchems/pubs/pmnpart1.pdf; EPA, *Instruction Manual for Reporting under the TSCA §5 New Chemicals Program*, at 24-30 (Feb. 2003 draft) *(PMN Instruction Manual)*, available at http://www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf; *Q&A Manual* at 1-22 - 1-29; 44 Fed. Reg. 2242, 2247 (Jan. 10, 1979) (chemical substances on the Inventory "will be identified individually by their specific chemical identities (*i.e.*, molecular formulae, chemical structures)"). Additional chemical identification requirements apply to polymers. *See* 40 C.F.R. § 720.45(a)(2).

[21] 40 C.F.R. § 720.45(a)(1); *see also* 60 Fed. Reg. 16298 (Mar. 29, 1995). For Class 2 substances "for which a definite molecular formula is known or reasonably ascertainable," the molecular formula also is required. *Id.*

> [F]or TSCA Inventory purposes, all substances are categorized by EPA into two groups according to the degree of certainty about the chemical structure of a substance: Class 1 and Class 2. Class 1 substances are those of precisely known chemical composition for which a single, complete structural diagram can be drawn. Class 2 substances are those having chemical compositions not completely definite or known; therefore, a Class 2 substance cannot be characterized by one definite, complete chemical structure diagram.[22]

In five separate Inventory nomenclature guidance documents issued subsequent to the March 1995 promulgation of the amended PMN rules, EPA provided guidance "to make it easier for the users of the Inventory to interpret listings . . . and to understand how [certain] new substances should be identified for Inventory inclusion."[23] The *Formulated and Statutory Mixtures Guidance* states that "'chemical substance' is defined in section 3 of TSCA (and in [EPA's] implementing regulations) by chemical composition, by source or origin and by

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22 60 Fed. Reg. at 16299; *see also Q&A Manual* at 1-29.

23 EPA, *Toxic Substances Control Act Inventory Representation for Polymeric Substances* (undated), available at http://www.epa.gov/opptintr/newchems/pubs/polymers.txt; EPA, *Toxic Substances Control Act Inventory Representation for Certain Chemical Substances Containing Carbon Chain Lengths (Alkyl Ranges Using the CX-Y Notation)* (undated), available at http://www.epa.gov/opptintr/newchems/pubs/alkyl-rg.txt; EPA, *Toxic Substances Control Act Inventory Representation for Combinations of Two or More Substances: Complex Reaction Products* (undated) *(Complex Reaction Guidance)*, available at http://www.epa.gov/opptintr/newchems/pubs/rxnprods.txt; EPA, *Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures* (undated) *(Formulated and Statutory Mixtures Guidance)*, available at http://www.epa.gov/opptintr/newchems/pubs/mixtures.txt; EPA, *Toxic Substances Control Act Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials: UVCB Substances* (undated) *(UVCB Guidance)*, available at http://www.epa.gov/opptintr/newchems/pubs/uvcb.txt.

identification of certain categories of materials that are not considered 'chemical substances.'"[24] The guidance leaves little doubt that "by chemical composition" was a reference to the introductory language in TSCA Section 3(2)(A) (*i.e.*, "any organic or inorganic substance of a particular molecular identity"), "by source or origin" was a reference to Section 3(2)(A)(i) ("any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature"), and "by identification of [excluded] categories of materials" was a reference to the mixture and other exclusions in Section 3(2)(B).

The *UVCB Guidance* discusses the subgroup of Class 2 chemical substances known as UVCBs, which are defined as "substances that have no definite molecular formula representation and either partial structural diagrams or no structural diagrams."[25] In particular, the guidance explains that "[e]ach name for a UVCB substance includes more than one molecular entity: as such, each UVCB can be considered to be a category of molecules, often closely related."[26] The guidance then states with respect to those UVCBs "not adequately described by their CA Names" that:

> [they] have supplemental definitions that are considered integral parts of the name for TSCA purposes. In general, the definitions

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24 *Formulated and Statutory Mixtures Guidance* at 1-2.

25 *UVCB Guidance* at 2; *see also Complex Reaction Guidance* at 2. The other two subgroups of Class 2 substances include "substances that can be represented by definite Hill ordered molecular formulas but have variable structural diagrams . . . [and] substances that can be represented by definite molecular formulas but have unknown structural diagrams." *UVCB Guidance* at 2.

26 *Id*. at 2.

> serve to narrow the scope of the CA Names. Thus, any substance that matches a CA Name on the TSCA Inventory but is not covered by the corresponding substance definition is not considered to be covered by that Inventory name.
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> . . .
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> Chemical substance definitions often include such information as the typical or allowed carbon number ranges or physical property ranges, the types of atoms or substances that may be included, and the raw material sources or processes of manufacture. Many definitions use a standard format. Typically, the first sentence states that the substance is a combination of substances of a certain class and indicates the nature or the process by which it was derived. The next sentence (or sentences) usually identifies the predominant components and perhaps an approximate boiling range or other characteristic physical data.[27]

For purposes of this analysis, it must be emphasized that neither the majority of existing engineered nanoscale materials nor the majority of existing chemical substances of which those nanomaterials are comprised constitute UVCB substances, in particular UVCBs "not adequately described by their CA Names." Instead, they are Class 1 substances -- substances of precisely known chemical composition for which a single, complete structural diagram can be drawn -- or Class 2 substances with a known molecular formula but either a variable or unknown structural diagram. In either case, the already-listed chemical on the TSCA Inventory does not contain a supplemental definition. Hence, the sole inquiry for purposes of determining the need

[27] *Id.* at 3-4.

for a PMN is whether the engineered nanoscale substance matches a CA Name on the Inventory.[28]

Since the inception of the TSCA regulatory program, then, EPA effectively has interpreted the phrase "particular molecular identity" as referring to a chemical substance's molecular formula and chemical structure and, where one already exists, the CASRN. This is fully in accord with the statutory language.

EPA, for example, does not require, for purposes of a *bona fide* intent (BFI) request under 40 C.F.R. Section 720.25(b), that a manufacturer or importer of a potentially new chemical substance provide EPA with information on the physical and chemical properties of the substance.[29] While EPA does require, as part of a PMN, the submission of "physical and chemical properties data" that are in the PMN submitter's possession or control, this stems from the fact that such data are considered "test data . . . related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal" of the

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[28] For a UVCB not adequately described by its CA Name, physical or chemical properties data that may be included in its supplemental definition rarely affect the determination of the chemical substance's identity.

[29] *See* 40 C.F.R. § 720.25(b). A person making a BFI request inquires whether a particular substance is included on the confidential portion of the TSCA Inventory. *Id.*

substance under TSCA Section 5(d)(1)(B).[30] Physical and chemical properties data, as EPA has explained, are used for risk assessment purposes.[31]

EPA's *Chemistry Assistance Manual* describes in detail the PMN review process that ensues once EPA receives a PMN.[32] The process consists of "four distinct, successive technical phases: the chemistry review phase, the hazard (toxicity) evaluation phase, the exposure evaluation phase and the risk assessment/risk management phase."[33] During the chemistry review phase, an initial chemistry review of the reported substance is first completed. The initial chemistry review "is a rapid assessment by [EPA] chemists of [the PMN] submission."[34] The submission is checked for "technical completeness" to verify that the substance is "identified correctly, as well as consistently," pollution prevention opportunities are identified, and the case is assigned to a chemist for preparation of a Chemistry Report.[35]

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30 40 C.F.R. § 720.50(a); *see also* 44 Fed. Reg. at 2252.

31 *Chemistry Assistance Manual*, *supra* note 5, at 16, 44-45. As the TSCA legislative history makes clear, "[t]he [PMN] requirements are intended to provide [EPA] with an opportunity to review and evaluate information with respect to the substance to determine if manufacture, processing, distribution in commerce, use or disposal should be limited, delayed or prohibited . . . ." H.R. Conf. Rep. No. 94-1679, at 65, *reproduced in TSCA Legislative History* at 678; *see also* H.R. Rep. No. 94-1341, at 23, *reproduced in TSCA Legislative History* at 430; *TSCA Legislative History* at 748 (statement of Rep. Murphy). For those UVCBs whose Inventory name includes a supplemental definition, as noted earlier, that supplemental definition must be consulted to determine whether a potentially new chemical substance is covered by that Inventory name.

32 *Chemistry Assistance Manual* at 22.

33 *Id.* at 6.

34 *Id.* at 13.

35 *Id.* at 13-15.

After completion of the initial chemistry review, EPA performs an "Inventory review" to determine whether the substance is a new or existing chemical substance:

> The Inventory review is an extremely important component of the PMN review process, from both legal and technical standpoints. The Inventory review, performed by chemists within [the Industrial Chemistry Branch], has two major functions. The first is to establish a complete and accurate chemical name for the new substance. The chemist compares the chemical structure, molecular formula, the reactants, and the reaction scheme for consistency with the CAS name submitted in the PMN; if a CAS Registry Number is provided, the chemist verifies it as well. The name must be consistent with CAS nomenclature policies and with how similar substances have been named previously for the TSCA Inventory. . . .
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> The second function of the Inventory review is to determine definitively that the new chemical substance is not (or is) on the TSCA Chemical Substance Inventory. For this search, the Agency uses the continually updated computer database of the Inventory, known as the Master confidential and non-confidential listings. . . . If the Inventory review establishes that a PMN substance is currently on the TSCA Inventory . . ., the substance is excluded from PMN reporting. . . . In [this] circumstance, Agency staff terminates the review and notify the submitter.[36]

When a substance is found to be an existing chemical substance, EPA notifies the submitter that "section 5 of [TSCA] does not prevent the manufacture or import of the substance" and ceases

[36] *Id.* at 15-16 (citations and footnotes omitted).

the PMN review process.[37] Only if a substance is not listed on the Inventory does EPA proceed to a Chemical Review Meeting.[38]

As indicated above, EPA's regulatory definition of "new chemical substance" mirrors the statutory definition: a "new chemical substance" is any chemical substance not listed on the TSCA Inventory.[39] In ascertaining whether a particular substance appears on the Inventory, all that matters is whether, based on the substance's molecular identity, it is or is not listed.[40] Thus, EPA's position always has been to treat different particle sizes with the same molecular identity as the same chemical substance. For example, a 10 micron grain of graphite and a 1 micron grain of graphite, although different particle sizes, are the same chemical

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37 40 C.F.R. § 720.62; *see also Q&A Manual* at 1-32 (describing the PMN review process and stating, "[t]he Inventory is checked to see if the subject material has already been listed. If the material is found on the TSCA Inventory, EPA will inform the submitter that they are free to commence non-exempt commercial manufacture of the new chemical substance."); EPA, *PMN Instruction Manual*, *supra* note 20, at 16.

38 *Q&A Manual* at 1-32; *see also* EPA, *New Chemicals Program* (May 1995), at 9 (PMN review process chart depicting "Search of the TSCA Inventory" prior to the "Chemical Review Meeting").

39 *See* 40 C.F.R. §§ 710.3, 720.3(v), 720.25(a).

40 *See* 69 Fed. Reg. 65565, 65567 (Nov. 15, 2004) (stating "[t]he only way to determine if a substance is new or existing is by consulting the TSCA Inventory"); 42 Fed. Reg. at 64591 (promulgation of the original Inventory reporting regulations, stating that the Inventory "defines what is a 'new chemical substance' for purposes of [the PMN requirements in] section 5(a)(1)(A).") It is noteworthy, too, that in the initial Chemical Substance Inventory Reports that enabled EPA to compile and publish the initial TSCA Inventory on June 1, 1979, manufacturers and importers were not required to report physical and chemical properties data for their respective chemical substances. EPA, of course, highlighted its lack of physical and chemical properties (and other) data for existing high production volume chemicals when it launched the voluntary High Production Volume Challenge Program in 1998. *See* 65 Fed. Reg. 81686, 81687-88 (Dec. 26, 2000).

substance -- graphite -- because they have the same molecular identity. Given the language of TSCA Section 3(2)(A), this is entirely correct.

PART II

II. TSCA PROVIDES EPA WITH AMPLE AUTHORITY TO ADDRESS POTENTIAL RISK FROM EXISTING CHEMICAL SUBSTANCES

As EPA knows from its almost 30 years of implementing the statute, TSCA provides EPA with ample authority to regulate existing chemical substances, including existing engineered nanoscale materials. The Panel offers below a summary overview of the key statutory provisions applicable to existing chemical substances, including engineered nanoscale materials. Review of these statutory provisions supports the Panel's view that TSCA's existing statutory provisions provide EPA with ample authority to address whatever risks existing engineered nanoscale materials may pose.

A. Section 4

TSCA Section 4 authorizes EPA to require manufacturers, importers and processors of existing chemical substances to conduct health effects, environmental effects, environmental fate and other types of needed testing "to develop data with respect to the health and environmental effects" of the chemical if EPA determines that a chemical substance may present unreasonable risk.[41] As EPA explained recently in the context of the potential voluntary pilot program for certain nanoscale materials, the statutory findings include:

> (1) there are insufficient data available to determine the effects of the substance on health and/or the environment; and (2) testing is necessary to provide such data; and (3)(a) the chemical may present an unreasonable risk of injury to health or the environment; and/or (3)(b) the chemical is or will be produced in substantial quantities and it enters or may be anticipated to enter the environment in substantial quantities, or there may be significant or substantial human exposure to the substance.[42]

As an alternative to rulemaking, EPA can obtain and often has obtained test data through its Enforceable Consent Agreement (ECA) process. ECAs are used where a consensus exists among EPA and interested parties and the public about the adequacy of a proposed testing program. Similar to Section 4 rules, ECAs are used to develop information on toxicological

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41 TSCA § 4(a), 15 U.S.C. § 2603(a).

42 EPA, "Considerations Relevant to Toxic Substances Control Act (TSCA) Application to Nanoscale Materials," EPA-HQ-OPPT-2004-0122-0010, at 1 (2005) (Relevant Considerations), available at http://www.regulations.gov/fdmspublic-rel11/ContentViewer?objectId=09000064800b046d&contentType=pdf&disposition=inline.

endpoints for human health and the environment. EPA's broad authority to compel testing under TSCA Section 4 also authorizes it to review and consider the data generated under a rulemaking and through an ECA and to impose, where necessary and appropriate, additional requirements on the existing chemical, including the generation of additional data. If a risk EPA believes to be "unreasonable" is found, EPA is authorized to impose restrictions on the chemical's manufacture, distribution, and/or use and disposal.

B. Section 5

TSCA Section 5(a) applies both to manufacturing and processing notices for new chemical substances and for significant new uses of existing chemicals.[43] Once EPA issues a Significant New Use Rule (SNUR), anyone who intends to manufacture, import or process a chemical for a significant new use must submit to EPA, at least 90 days in advance, a Significant New Use Notice (SNUN).[44] SNUNs and PMNs undergo the same review by EPA and "provide EPA with an opportunity to evaluate . . . significant new uses . . . and, if necessary, prohibit or limit activities associated with the . . . uses before they occur."[45] If EPA makes certain determinations -- "that insufficient information exists to evaluate the human health and environmental effects of the chemical, and that: (1) [the chemical] may present an unreasonable

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43 TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2). While EPA, in making a significant new use designation, is mandated to consider "all relevant factors," no risk determination is required for the issuance of a SNUR. *Id.*

44 TSCA § 5(a)(1)(B), 15 U.S.C. § 2604(a)(1)(B).

45 Relevant Considerations at 1-2.

risk . . . or (2) it is or will be produced in substantial quantities, and there is or will be substantial or significant exposure/release"[46] -- it may unilaterally propose a Section 5(e) order or negotiate an order, *i.e.*, a Section 5(e) Consent Order, that imposes restrictions on the existing chemical substance.

Additionally, if EPA determines that the manufacturing, processing, distribution in commerce, or disposal of a chemical that is the subject of a PMN or SNUN presents or will present an unreasonable risk before EPA is able to issue a TSCA Section 6 rule, EPA is authorized to issue a TSCA Section 5(f) order. Such an order could limit the manufacture of a chemical, impose other restrictions through an immediately effective proposed rule or prohibit the manufacture, processing, or distribution in commerce of a chemical through a proposed order or by seeking a court order.

Finally, in certain cases, PMN or SNUN submitters may voluntarily agree to suspend the notice review period and conduct hazard and/or environmental fate testing in response to a request from EPA.

In short, TSCA Section 5 offers EPA a wide variety of mechanisms to obtain additional information on existing chemical substances and/or restrict or prohibit the manufacture, processing and/or distribution in commerce of existing chemical substances. Chemical manufacturers have also evidenced significant receptivity to voluntary and other

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[46] EPA, "EPA Authorities Under TSCA" (July 11, 2005) at 14, available at http://www.epa.gov/oppt/npptac/pubs/tscaauthorities71105.doc.

innovative approaches to provide EPA with additional information about existing chemical substances when EPA has expressed obtaining such information.

C. Section 6

TSCA Section 6(a) authorizes EPA to regulate the manufacture, processing, commercial distribution, use and/or disposal of an existing chemical substance when there is a reasonable basis to conclude that the substance "presents or will present an unreasonable risk of injury to health or the environment."[47] Specifically, EPA may promulgate a regulation:

- prohibiting or limiting the manufacture, processing or distribution in commerce of the chemical;
- prohibiting or limiting the manufacture, processing or distribution in commerce of the chemical for a particular use or for a particular use at a particular concentration;
- requiring that the chemical, or any article containing the chemical, be labeled or accompanied by warnings and instructions for use, distribution or disposal;
- requiring that manufacturers and processors of the chemical maintain records of manufacturing/processing methods and conduct reasonable monitoring or testing necessary to assure regulatory compliance;
- prohibiting or otherwise regulating commercial use of the chemical;
- prohibiting or otherwise regulating disposal of the chemical, or any article containing the chemical, by manufacturers, processors or anyone who uses, or disposes of, it for commercial purposes; or

[47] TSCA § 6(a), 15 U.S.C. § 2605(a).

- requiring manufacturers or processors to notify distributors, other persons in possession of the chemical and the general public of the unreasonable risk of injury and replace or repurchase the chemical.[48]

TSCA Section 6(b) authorizes EPA to order a manufacturer or processor to provide certain information to EPA if EPA has a reasonable basis to conclude that the manufacture or processing of an existing chemical substance may present an unreasonable risk to human health or the environment. EPA may, for example, order the manufacturer or processor to submit a description of the chemical substance's quality control procedures. EPA is authorized to require the manufacturer or processor to modify those procedures to the extent EPA believes necessary to address any inadequacies. Further, under TSCA Section 6(b), if EPA determines that a chemical that has been distributed presents an unreasonable risk, EPA is authorized to order the manufacturer or processor to notify its customers and the public of the risk and to replace or repurchase the chemical, as appropriate, to abate the risk.

TSCA Section 6 thus offers EPA yet more opportunities, tools and mechanisms for EPA to address and abate any potential risk from existing engineered nanoscale substances consisting of chemical substances that EPA determines to be unreasonable. TSCA Section 6(a) rules and 6(b) quality control orders complement the authorities under TSCA Sections 4 and 5 and address a wide spectrum of commercial circumstances that could pose risk to human health and/or the environment.

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[48] TSCA § 6(a)(1)-(7), 15 U.S.C. § 2605(a)(1)-(7).

D. Section 7

TSCA Section 7 authorizes EPA to initiate a civil action to seize an imminently hazardous substance, mixture or article containing them, and seek such other relief against any person who manufactures, processes, distributes, uses, or disposes of an imminently hazardous substance, mixture or article containing them. EPA's authority under TSCA Section 7 is broad and authorizes EPA to seek judicial relief empowering it to order the manufacturer, processor or distributor or others to recall, replace/repurchase, publish notice of risk and notify purchases of the risk or a combination of any of these requirements.

E. Section 8

EPA has broad information-gathering powers under TSCA Section 8. These powers include the ability to impose, under Section 8(a), recordkeeping and reporting requirements for production, use and exposure-related information and, under Section 8(d), "health and safety study" submission requirements. Pursuant to regulations issued by EPA under Section 8(c), manufacturers, importers and processors of an existing chemical substance must create and maintain records of "allegations" -- whether written or oral -- that the chemical "caused a significant adverse reaction to health or the environment."[49] A company's Section 8(c) records must be made available for inspection by EPA at any time and submitted to EPA

[49] 40 C.F.R. § 717.3(a).

upon request.[50] Failure to maintain, submit or permit access to records or reports is punishable by both civil and criminal penalties.

Finally, Section 8(e), the self-executing substantial risk reporting provision of TSCA, "requires, on an ongoing basis, that persons manufacturing, importing, processing, or distributing [an existing chemical substance] in commerce must immediately inform EPA if they obtain information that reasonably supports the conclusion that the chemical substance . . . presents a substantial risk of injury to health or the environment."[51] Historically, penalties for non-compliance with this reporting obligation have been severe.

TSCA provides EPA with broad, diverse and multiple authorities and tools to address and abate risks believed to arise from existing chemical substances. EPA is empowered under these TSCA provisions to invoke its authority when and if the manufacture, processing, distribution in commerce, use and/or disposal of an existing engineered nanoscale material is believed to pose the kind of risk that authorizes EPA to implement its authority. As manufacturers and processors of existing engineered nanoscale materials, the Panel strongly believes that the breadth, diversity and scope of EPA's current authorities under TSCA are more than adequate to address any risk to human health and/or the environment that any existing engineered nanoscale material -- or any other existing chemical for that matter -- may be found to pose. Accordingly, and for all the reasons noted above, neither determining existing

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50 *Id.* § 717.17(a)-(b).

51 Relevant Considerations at 3.

engineered nanoscale materials are "new" chemical substances nor seeking new legislative grants of authority are necessary or appropriate. As presently written and implemented, TSCA is adequate and well suited to address whatever risk engineered nanoscale materials may be found to pose.

CONCLUSION

For the foregoing reasons, the inclusion or non-inclusion of a particular substance's molecular identity on the TSCA Inventory determines whether it is a new or existing chemical substance under TSCA. Precisely because it has a molecular formula and chemical structure identical to a chemical already on the Inventory, an existing engineered nanosacle material, irrespective of its physical and chemical properties, constitutes an existing chemical substance under TSCA. As an existing chemical substance, it can be regulated, if necessary, under the provisions of TSCA outlined above applicable to existing chemical substances. These provisions provide EPA with adequate authority to address any potential risk existing engineered nanoscale materials may be found to pose.

The Panel hopes that you find this information useful and would be pleased to discuss this matter in more detail with EPA.