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Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Attention: Docket ID No. EPA-HQ-OPPT-2010-0572

The purpose of this letter is to provide comments on behalf of the International Center for Technology Assessment, the Center for Food Safety, the Center For Biological Diversity, and the Institute on Agriculture and Trade Policy in reference to the Toxic Substance Control Act (TSCA or the Act) Section 8(a) Proposed rule: *Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements*.[1]

We applaud the effort made by the U.S. Environmental Protection Agency (EPA) in taking this necessary step to gather information on the physical and chemical properties of nanochemicals and their potential hazards. This action will prove all the more important as many nanomaterials are manufactured and sold in the United States.

Engineered nanomaterials present uncertain risks to human health and the environment; therefore, we wish to express our general support of EPA's proposed rule.

At the same time, it is essential that EPA rulemaking establish unambiguous definitions, more frequent reporting, meaningful testing, and publically accessible databases in order to address the evolving nature of nanomaterials. However, the EPA should not spend an inordinate amount of time establishing these definitions and might well consider using definitions developed in France, which have resulted in significant reporting in the last two years.

In these comments, we first provide specific recommendations on the proposed rule; and second, we urge EPA to fully implement additional TSCA provisions to regulate nanomaterials.

I. EPA Should Revise the Proposed Rule to Encompass the Following Thirteen Recommendations:

[1] 80 Fed. Reg. 18,330 (April 6, 2015).

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The need for research on the health and safety effects of exposure to nanomaterials is widely recognized. While this proposed rule is an admirable step toward gathering existing data, collecting data alone will not be enough to protect human health and the environment. Collecting the right data and enough data must also be a goal of the data call-in. Furthermore, the data must be submitted according to a common data template of EPA-defined data elements to enable the agency to aggregate data sets that will enable risk assessment of individual and compound nanomaterials according to their exterior and interior dimensions, shapes, and properties.

The health impacts of exposure to nanomaterials throughout their lifecycles are not known, nor are the environmental impacts. Therefore, it is imperative to generate meaningful data on engineered nanomaterials to enable risk assessment and risk-management decisions. If data shows that a nanosized chemical substance poses an unreasonable risk to workers and others, it will allow manufacturing and processing restrictions to be implemented.

1. **The Rule Should Define All Nanosized Chemical Substances as "New Chemical Substances."**

After data collection and review under this proposed regulation are completed, further rulemaking should declare gross chemical substances included on the chemical substance list published by EPA under section 2607(b) of the Toxic Substances Control Act to be different legally from the nanosized versions of those chemicals.

Presently, EPA sometimes uses Significant New Use Rules (SNUR), especially for carbon nanotubes. This is inadequate; EPA must treat nanosized chemicals as new chemicals, not just new versions of old chemicals. Without a regulation or new legislation that differentiates between nano and non-nanosized chemicals, manufacturers and processers will not be required to test their nanosized chemical substances and report the health and safety effects, nor will EPA be able to regulate nanosized chemical substances any differently from the bulk chemical substances they derive from.

Nanomaterials (as evidenced by the need to define "discrete forms" of nanomaterials in this proposed rule) have different physical properties from their bulk forms; therefore, the two chemicals should not be regulated the same way. If the two are regulated as if they are the same chemical substance, the public will not be protected from the potential hazards of nanomaterials. If nanosized chemical substances are not considered "new chemical substances," a data call like the one proposed in this rule will be of little use in the future. EPA should define each nanosized chemical substance as a "new chemical substance" under the Act. Thus, EPA would be better able to access and respond to any unforeseen environmental and public health challenges.

Furthermore, given the rapidly growing use of nanomaterials, decision makers must not allow nano chemical products on the market by considering them simple variants of the bulk form without adequate nano-specific test results. Precautionary protective actions must be implemented and the uncertainties and gaps in knowledge should not be an excuse to allow a product on the market.

2. **The Requirement That Reportable Nanosized Chemical Substances Exhibit "Unique and Novel Characteristics" Should Be Stricken.**

In the proposed rule, EPA would require the reporting of nanosized chemicals when they are in their solid form, are between 1 and 100 nanometers, and when they exhibit "unique and novel characteristics or properties because of their size."

We recommend that EPA strike the last requirement which specifies nanosized chemical substances must be "unique and novel" to fall within the reporting requirement. This is too vague and leaves too much interpretation to manufacturers to determine whether they are required to comply with this law. Moreover, the three factors discussed below already describe which kinds of "unique and novel" properties should be examined.

Any one or more of the three factors for identifying "discrete forms" of nanomaterials should be enough to trigger reporting.

In the proposed rule, EPA proposes that "discrete forms" of nanosized chemical substances are reportable if they can be distinguished based on a total of three factors:

> 1) Process has been changed to alter the substances' size, properties, or both;
>
> 2) Mean particle size has been altered by ten percent or more;
>
> 3) Measured change in zeta potential, specific surface area, dispersion stability, or surface reactivity exceeds seven times the standard deviation of the measured values.

EPA should revise subsection (a)(1) of the proposed rule so that the existence of any one or more of the factors is sufficient to trigger reporting as a "discrete form."

A change in just one of the factors could change the toxicity of the substance.

Additionally, there is no mention of how manufacturers and processors are to determine whether any of these three factors exists, nor is there a requirement that manufacturers or processors test for such factors. Often, the distinct properties of nanomaterial only become apparent after testing for the specific properties. Moreover, EPA might consider adding changed shape and/or configuration as a factor. Testing for all of those properties should be mandatory or, alternatively, EPA could simply require reporting for any chemical smaller than 100nm.

3. **EPA Should Provide Guidance on Testing Nanosized Chemical Substances to Determine Whether They Are "Discrete Forms."**

In the proposed rule, EPA recommends, but does not require, "using the same medium or method when measuring the change in these properties" because even minor changes can result in a large difference in the measured result. However, as stated above, no testing method is specified.

The final rule should specify the methods that will be used to determine the three factors in (a)(1). The final rule should also explain how to test nanomaterial compounds any of which could impact test results.

Without such guidance, companies will not have the analytical tools to make the distinctions among "discrete forms" of nanomaterials.

4. The Definition of "Release Information" Needs to Be Expanded.

The definition of "release information" should include any potential unintended releases into the environment (spills, fires, etc.) and releases during storage, transportation, recycling, and degradation. Inclusion of these elements would ensure that data are submitted, which will help both regulators and safety personnel make informed decisions on the health and safety risks of various nanomaterials.

5. EPA Should Require Testing and Data Submission Based on Nanosized Chemical Substances Themselves and Not on "Structural Analogs" of a Nanosized Chemical Substance Which May Not Exist.

EPA's decision to use data from a "structural analog" of a nanochemical if data are not available for that chemical raises serious concerns. Despite a high chemical similarity, structural analogs are not necessarily functional analogs, and can have very different physical, chemical, and biochemical properties. Usually, size, form, and specific chemical composition define the functionality of nanoscale materials, and "structural analogs" may or may not behave in a similar way. Using existing data on "structural analogs" may result in the use of inappropriate data to make these determinations that miss how the nano chemical actually functions. EPA must require testing of the nanosized chemical substances where there are not adequate data to make a health and safety determination.

6. The Location of Exposed Workers Should Be Publicly Available Information.

Workers who manufacture or process nanomaterials are often the first to be exposed to the potential hazards of novel chemical substances. In public health, the population of exposed workers is often used to monitor exposure, determine potential short-term and long-term health effects, and establish "hierarchy of control" measures to minimize exposures (e.g., engineering, administrative, and personal protective equipment). Very little is known about how the working population is being exposed to nanosized chemical substances; even less is known about the locations of the workers' exposures. This lack of occupational-exposure information prevents adequate monitoring in order to determine potential public health effects and how to reduce

subsequent exposures. Therefore, we suggest that the final rule include not only the estimated number of people exposed by places of employment, but also include their workplace locations.

7. The Proposed Definition of "Small Manufacturer or Processor" Should Be Amended.

We support EPA's decision to provide a different definition of "small manufacturer or processor" specific to these reporting requirements because of the unique circumstances under which nanomaterials are manufactured and processed. EPA should amend the definition of "small manufacturer or processor" to have an even lower threshold so that it includes only companies that have less than $1 million per year in annual sales and produce less than 100 grams of nanomaterials. There are many start-ups and other small businesses that make various nanomaterials, often for the first time. Due to the uncertainty surrounding the potential hazards of nanomaterials, even relatively small businesses should be required to report their data. A dollar limit should be coupled with a volume limit. For example, the French require mandatory annual reporting from any facility that produces, imports, or distributes a minimum quantity of 100 grams of nano substances in a year. In 2014, 10,417 declarations were submitted, compared to 3,409 declarations submitted for 2013.[2]

8. EPA Should Require All Nanoscale Materials Already in Commerce to Update Previous Voluntary Data Submissions or Report Original Data Under this Proposed Rule.

In its Proposed Rule, EPA states "Nanoscale materials based on chemical substances already on the TSCA inventory are considered existing chemical substances. These nanoscale materials do not require reporting as they are nanoscale forms of chemicals already in commerce."[3] This is inadequate.

EPA estimated that its voluntary reporting program for existing nanoscale material production from January, 2008–December, 2009 provided information on only about ten percent of chemical substances manufactured at the nanoscale and commercially available in 2009.[4] EPA should require updates from those who previously voluntarily reported, and require all manufacturers of chemicals manufactured at the nanoscale who did not previously report and have chemical substances in commerce to comply with this reporting rule, including those which are considered nanoscale forms of existing chemicals.

The French experience makes it clear that a one-time data call is not adequate. The proposed rule exempts manufacturers that filed pre-manufacturing notices and significant new use notices after January 1, 2005 from the proposed reporting requirements. EPA should consider a later pre-manufacturing notice date such as January 1, 2015 as a basis for such exemption.

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[2] http://www.developpement-durable.gouv.fr/IMG/pdf/rapport-nano-2014.pdf
[3] 80 Fed. Reg. 18,330, 18,334 (April 6, 2015).
[4] *Id.*

Nanotechnology is a rapidly evolving field. It is highly likely that some of these materials and how they are used have changed considerably over the past ten years. The proposed reporting rule offers an opportunity to evaluate how uses of these newer materials have developed in recent years, including potentially significant changes in production volume. Given the large number of nanomaterials reviewed over the past decade and the rapid pace of technological evolution, only the most recent pre-manufacturing notices should be considered for this exemption.

If insufficient data is provided, EPA must notify the manufacturer that it cannot determine potential impacts, and thus continue to hold back under review any pre-manufacturing notice. For materials already circulating in the market, EPA should take action, or establish procedures to remove them from commerce.

9. EPA's Production Threshold for Covered Chemicals Is Still too Large.

EPA correctly argues that a significant reduction in the production volume for a reporting threshold for nanoscale materials (down to 22,000 pounds, or ten metric tons) was necessary because otherwise the majority of nanoscale material manufacturers would be exempt from the proposed rule. However, even ten tons is large enough to miss much new nanochemical production; the reporting threshold should be reduced even more, perhaps to as low as 100 grams as the French have done, to capture new products in development. Additionally, the threshold should not be the same as conventional materials at 100,000 pounds, or else the new products will move into the market un-reviewed.

10. Nanoclays, Nano Films, and Nano Zinc Oxide Should Not Be Exempt.

EPA proposes to exclude from reporting these three types of nanomaterials because the data on these substances is "well-characterized or they present little exposure potential." However, current data on these materials is different from what was available in 2009, when this rulemaking began. The exclusion of these nanomaterials ignores that compounds such as nanoclays and nano zinc oxide are used in many nano enabling food packages. Even naturally occurring materials, when they are processed at a nanoscale, may have properties that affect human health. Exempting these three substances—or any specific nanosized chemical substances—from the proposed requirements is unwise; health and safety data on these materials are still emerging.

11. Integrate the Reported Data with Existing Databases on Nanochemicals.

Because of the paucity of information on the environmental, health and safety of nanomaterials, data reported under this regulation should not just be placed in the existing TSCA inventory, but should also be merged with other databases like www.nanomaterialregistry.org and databases developed as part of the National Nanotechnology Initiative. An aggregated searchable, up-to-date database of nanochemicals with curated data that is available to the public could enable the

environmental, health, and safety communities closer to understanding the effects of this emerging technology.

12. Confidential Business Information Claims Must Be Limited.

EPA must employ strict criteria for what is to be considered confidential business information. A baseline for the types of health, safety, and environmental impact data that must be provided to the public is essential. For example, key information, such as safety data sheets, should never be considered confidential, but must be made fully available to the public.

13. Adequate Funding Is Needed.

Finally, to evaluate the submitted data in a timely manner, EPA must have adequate resources allocated to conduct the work.

II. EPA Must Fully Implement TSCA to Ensure the Safety of Nanoscale Materials

While we support the reporting rule for nanoscale materials, we further urge EPA to take robust action under TSCA to make sure that nanoscale materials are safe before they are distributed in commerce. It is imperative that EPA take action now under TSCA rather than relying on a flawed presumption of safety until nanoscale materials have already caused damage to human health or the environment. The scientific evidence indicates nanoscale materials require regulation on their production, distribution, and use.

Congress enacted TSCA,[5] "to assure that … innovation and commerce in … chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment."[6] Accordingly, lawmakers required those responsible for the manufacture and processing of these compounds to develop "adequate data" describing their effects, and authorized EPA to devise and implement reasonable controls to prevent the risk of injury to health or the environment.[7]

EPA is also obligated to comply with the Endangered Species Act[8] and to assure that any action taken pursuant to TSCA does not affect threatened or endangered species and must consult with the expert agencies when necessary.[9]

EPA can and must also promulgate a significant new use rule, a test rule, and where necessary, regulate unsafe nanoscale materials from cradle to grave through section 6 rules.

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[5] 15 U.S.C. §§ 2601-2697.
[6] *Id.* § 2601(b)(3). Within the meaning of TSCA, the term "chemical substance" includes "any organic or inorganic substance of a particular molecular identity." *Id.* § 2602(2).
[7] *Id.* § 2601(b)(1), (2).
[8] 16 U.S.C. §§ 1531 *et seq.*
[9] *Id.* § 1536-1544.

1. Significant New Use Rule

EPA can and should develop a significant new use rule for nanoscale materials. Such a rule would require any person who processes, manufactures, or imports a nanoscale material for a significant new use to notify EPA at least ninety days before commencing the activity.[10] This would allow EPA to consider the environmental and human health risks of the use. This would allow EPA to therefore regulate the nanoscale material use as necessary to avoid an unreasonable risk to the environment or human health.

Nanoscale materials meet some or all of the criteria of a significant new use rule:[11]

(A) the projected volume of manufacturing and processing of a chemical substance;
(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and
(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

As described in these comments, nanoscale materials meet several of these factors and EPA should develop a significant new use rule to ensure the safety of these chemical substances. Moreover, significant new use rules can apply to categories of chemical substances.

Additionally, to the extent that EPA considers nanomaterials existing chemical substances based on their chemical structure, that policy is unsupported by the science and must change. This approach arbitrarily removed important opportunities for EPA to regulate the chemicals before they are manufactured.[12]

2. Test Rule

EPA must promulgate a test rule for nanoscale materials. TSCA provides for testing to determine toxicity, persistence, and other characteristics which affect health and the environment and are necessary to determine if there is an unreasonable risk of injury to health or the environment.

EPA must determine the health and environmental risks associated with a particular chemical substance, and the agency "*shall* by rule require that testing be conducted on such substance."[13] Section 4 of the Act authorizes EPA to compel manufacturers and processors to evaluate the safety of substances that "may present an unreasonable risk of injury to health or the environment" or that "[are] or will be produced in substantial quantities" and, thus, "may

[10] 15 U.S.C. § 2604(a)(1)(B).
[11] *Id.* § 2604(a)(2).
[12] *Id.* § 2604(a)(1).
[13] *Id.* § 2603 (emphasis added).

reasonably be anticipated to enter the environment in substantial quantities" or result in "significant or substantial human exposure."[14]

In enacting TSCA, Congress declared that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[15] Accordingly, section 4 directs EPA to require additional testing upon determining that "the manufacture, distribution in commerce, processing, use, or disposal of chemical substance or mixture … may present an unreasonable risk of injury to health or the environment," or if the chemical is produced in substantial quantities and there is a potential for a substantial quality to be released into the environment.[16]

Because nanoscale materials may present an unreasonable risk to the environment, they warrant a test rule. EPA interprets "may present an unreasonable risk" to mean that there is a "substantial (i.e., more than theoretical) probability" of unreasonable risk to the environment or health.[17] As described in these comments, nanoscale materials likely present an unreasonable risk to human health and the environment; and EPA must make a test rule for all nanoscale materials produced in large quantities. EPA established a threshold value of one million pounds for a release of a chemical to be substantial.[18]

3. Section 6 Rules

Section 6 of TSCA mandates that EPA "shall" regulate a chemical substance for which

> there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment.[19]

Permissible regulations include requirements prohibiting or "limiting the amount of such substance … which may be manufactured, processed, or distributed in commerce."[20] EPA can also require processors "to give public notice of such risk [of injury], and . . . to replace or repurchase such substance . . . to adequately protect health or the environment."[21] In assessing risk, EPA must consider:

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[14] *Id.*
[15] *Id.* § 2601(b)(1).
[16] *Id.* § 2603(a)(1)(A), (B)(i).
[17] *Chemical Mfrs. Ass'n v. EPA*, 859 F.2d 977, 988 (D.C. Cir. 1988).
[18] *TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure*, 58 Fed. Reg. 28736, 28746 (May 14, 1993).
[19] 15 U.S.C. § 2605(a) (emphasis added).
[20] *Id.* § 2605(a)(1)(B).
[21] *Id.* § 2605(b)(2)(B).

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture;
(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and
(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.[22]

Here, TSCA requires that EPA determine whether chemical substances produced at nanoscale present an unreasonable risk to human health or the environment. Accordingly, EPA must weigh these factors and fully evaluate the risk of nanoscale materials. Factual certainty is not required; instead, the agency may "base its action on scientific theories, consideration of projections from available data, modeling using reasonable assumptions, and extrapolations from limited data."[23] EPA has a duty to protect public health and the environment by making these findings for nanoscale chemical substances and regulating them accordingly under section 6 of TSCA.

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Thank you for the opportunity to comment.

Respectfully submitted,

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[22] *Id.* § 2605(c)(1). E.
[23] Lead Fishing Sinkers; Response to Citizens' Petition and Proposed Ban, 59 Fed. Reg. 11,122, 11,138 (Mar. 9, 1994) (*citing* H.R. Rep. No. 1341, 9th Cong., 2d Sess. 32 (1976)).