BEFORE THE NATIONAL GREEN TRIBUNAL

SOUTHERN ZONE BENCH AT CHENNAI

ORIGINAL APPLICATION NO: 66 OF 2017

IN THE MATTER OF:-

VALLAPUREDDY GARI GOVARDHAN REDDY & ORS.... ...Applicants

Versus

UNION OF INDIA & ORS ... .Respondents

INDEX

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PLACE: Chennai DATE: 25.11.2021

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ADDITIONAL AFFIDAVIT ON BEHALF OF INTERVENERS

1. I, Dr K Babu Rao S/o Lakshminarayana, R/o H.No.4-1-50/2, Road No 3, Snehapuri Colony Hyderabad, Telangana-500076, aged about 74 years presently in Hyderabad do hereby solemnly affirm and declare as under:

2. That I am the Intervener in the above mentioned application and I am fully conversant with the facts and circumstances of the case and therefore competent and I am authorized to swear this affidavit on behalf of the Interveners.

3. That this Hon'ble NGT (SZ) vide its order dated 28.9.2021 allowed the Application for impleadment filed by us and directed to furnish the regulatory mechanism adopted by other countries and whether EIA studies are conducted before permitting such industries in those countries. In continuation of our search for relevant content of the regulations that specify mandatory EIA for chemicals (conventional and nanoform), we could find highly relevant material from the USEPA and the European Union. Relevant pages are extracted from these documents and put together as an Annexure to this affidavit.

4. We have spent long hours everyday searching for nanomaterial environmental assessment related documents in several countries. In the process we saw thousands and thousands of documents covering some aspect of nanomaterial regulation. In contrast, in India we have no regulations for nanomaterials. Department of Science and Technology is promoting and funding nanotechnology and science research but all it has is rudimentary safety guidelines for handling nanomaterials. Our main concern as brought out in our implead petition was leaving out a class of substances that are of great

regulatory concern all over the world. MoEF&CC while applying its EIA notification 2006 for nanofertilizers flatly rejecting the same for a large 700 TPD nanomaterial production plant is a clear case of double standards and environmental injustice to workers of the plant and people living near the plant. Nano Boron, Nano Zinc and nano Copper are not merely plant micronutrients and have several more applications. Nano copper "acts as an anti-biotic, anti-microbial, and anti-fungal agent when added to plastics, coatings, and textiles" and has many other uses. Similarly nano zinc oxide is used for "nano-electronic/nano-optical devices, energy storage, cosmetic products, nanosensors". Based on the logic of the MoEF&CC there is no need to obtain environmental clearance for manufacture of nano copper, nano zinc and nano boron if they are not suffixed as fertilizers and are made for other applications. There would be no need to go through the permit process under EIA notification 2006 for nano silver as a biocide that is banned in several countries. It is for this contradictory skewed logic that Hon'ble NGT may not allow the policy harms the environment and people and violates the precautionary principle.

5. DIRECTIVE 2011/92/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment in its ANNEX I under article 6 "Integrated chemical installations, i.e. those installations for the manufacture on an industrial scale of substances using chemical conversion processes, in which several units are juxtaposed and are functionally linked to one another and which are:" includes in (b) the production of basic inorganic chemicals. As explained in the earlier additional affidavit submitted EU includes nanoform of chemicals under conventional chemical but as a separate form. As a proof a page from ECHA website https://echa.europa.eu/registration-dossier/-/registered-dossier/16050 printed as a pdf document is attached for reference.

6. An October 2012 published document on Impact Assessment as an accompanying document of "PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL" in Annex 1: Information on the EIA Directive on page 59 specifies **"Mandatory EIA: All projects listed in Annex I are considered as having significant effects on the environment and require an EIA"** (Emphasis added)

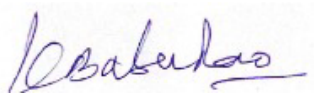
7. European Commission document on "Interpretation of definitions of project categories of annex I and II of the EIA Directive" in addition to repeating the production of basic inorganic chemicals as covered under 6 (b) of Annex I, it further elaborates on the chemicals covered with examples under "Inorganic chemicals include: (a) gases, such as ammonia, chlorine or hydrogen chloride, fluorine or hydrogen fluoride, carbon oxides, sulphur compounds, nitrogen oxides, hydrogen, sulphur dioxide, carbonyl chloride; (b) acids, such as chromic acid, hydrofluoric acid, phosphoric acid, nitric acid, hydrochloric acid, sulphuric acid, oleum, sulphurous acids; (c) bases, such as ammonium hydroxide, potassium hydroxide, sodium hydroxide; (d) salts, such as ammonium chloride, potassium chlorate, potassium carbonate, sodium carbonate, perborate, silver nitrate; (e) nonmetals, metal oxides or other inorganic compounds such as calcium carbide, silicon carbide." It also interprets that scale of manufacture is not a criteria saying 'Manufacture on an industrial scale' - Annex I(6) contains no quantitative capacity thresholds but only a reference to 'manufacture on an industrial scale'. This was the result of a ruling of the Court in Case C-133/94, Commission v Belgium stating "whether a chemical installation is integrated does not depend upon its processing capacity or on the type of chemical substance processed in it but on the existence of interlinked production units constituting in terms of their operation a single production unit". In the present case the scale operation is substantially high at 700 TPD.

8. We observed from the documents present on the US, EU and OECD regulatory system websites that these bodies have done enormous work on risk and life cycle assessment of the nanomaterials and also on safety. We present here two examples from USEPA on comprehensive environmental assessment for multiwalled carbon nanotubes and nano silver. Relevant pages of these documents are attached with the affidavit. USEPA issued a final rule on "Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements" in January 2017. "*As indicated in the proposed rule, the requirements of the rule are not based on an assumption that nanoscale materials as a class, or specific uses of nanoscale materials, necessarily give rise to or are likely to cause harm to people or the environment. Rather, any information gathered under this rule will facilitate*

EPA's determination of whether further action, including additional information collection, is needed for that specific nanoscale material. Consistent with the President's memorandums for Executive Agencies regarding Principles for Regulation and Oversight of Emerging Technologies and U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials (Ref. 3), this rule will facilitate assessment of risks and risk management, examination of the benefits and costs of further measures, and making future decisions based on available scientific evidence." Despite all the knowledge generation on nanomaterial risk and life cycle assessment, safety and comprehensive evolving regulation systems, Office of Inspector General in its review observed "EPA Needs to Manage Nanomaterial Risks More Effectively". How do we rate complete absence of any regulations for nanomaterials and hiding behind policy? Similarly, OECD has also done extensive work on regulation of nanomaterials. A webpage copied as a pdf document to show more than 100 studies published on safety of manufactured nanomaterials. Small countries like Malaysia, a member of OECD, are applying strict regulations for nanomaterials. We tried to get hold of a copy of the EIA for manufacture of graphene in Malaysia but could not get. Malaysia's department of Occupational Safety and Health published a "Guideline on Control and Safe Handling of Nanomaterials" in 2018 based on published peer reviewed articles. WHO also published "WHO guidelines on protecting workers from potential risks of manufactured nanomaterials" in 2017. *"Guiding principles: The Guideline Development Group (GDG) used a precautionary approach as one of its guiding principles. This means that exposure has to be reduced, despite uncertainty about the adverse health effects, when there are reasonable indications to do so. In addition, the hierarchy of controls was an important guiding principle. This means that when there is a choice between control measures, those measures that are closer to the root of the problem should always be preferred over measures that put a greater burden on workers, such as the use of personal protective equipment (PPE)."* [Page 5]

9. In view of the above evidence that all the EU countries are mandated to conduct EIA studies for all basic inorganic chemicals manufacture, and the nanoform is a special case of the bulk conventional inorganic chemical, it is prayed that the MoEF&CC may be directed to include all nanochemicals under

EIA notification, especially in the absence of any 'Nanotechnology Regulatory Board' to take care of the proper of assessment of environmental, occupational and human health impacts that could result from production of nanochemicals. In USA and OECD countries also there are strict regulations for nanomaterials and are subjected to regular inspections and safety norms. Giving blanket permissions to risky nanomaterial manufacture stating that "***at present there is no requirement to bring manufacture ofprecipitated calcium carbonate nanoparticles under the ambit of the EIA Notificaiton 2006"*** is a case of environmental injustice, hence this Hon'ble Tribunal may rectify the same.

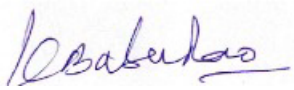


Dr K Babu Rao

Dr A V Rao
DEPONENTS

VERIFICATION: -

Verified on this the 25th day of November, 2021 that the contents of the above affidavit are true and correct. No part of it is false and nothing material has been concealed therefrom.



Dr K Babu Rao
DEPONENTS

Dr A V Rao

Through

SRAVAN KUMAR
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I

ANNEXURE A1

(Legislative acts)

DIRECTIVES

DIRECTIVE 2011/92/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 December 2011

on the assessment of the effects of certain public and private projects on the environment

(codification)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment [3] has been substantially amended several times [4]. In the interests of clarity and rationality the said Directive should be codified.

(2) Pursuant to Article 191 of the Treaty on the Functioning of the European Union, Union policy on the environment is based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified at source and that the polluter should pay. Effects on the environment should be taken into account at the earliest possible stage in all the technical planning and decision-making processes.

(3) The principles of the assessment of environmental effects should be harmonised, in particular with reference to the projects which should be subject to assessment, the main obligations of the developers and the content of the assessment. The Member States may lay down stricter rules to protect the environment.

(4) In addition, it is necessary to achieve one of the objectives of the Union in the sphere of the protection of the environment and the quality of life.

(5) The environmental legislation of the Union includes provisions enabling public authorities and other bodies to take decisions which may have a significant effect on the environment as well as on personal health and well-being.

(6) General principles for the assessment of environmental effects should be laid down with a view to supplementing and coordinating development consent procedures governing public and private projects likely to have a major effect on the environment.

(7) Development consent for public and private projects which are likely to have significant effects on the environment should be granted only after an assessment of the likely significant environmental effects of those projects has been carried out. That assessment should be conducted on the basis of the appropriate information supplied by the developer, which may be supplemented by the authorities and by the public likely to be concerned by the project in question.

[1] OJ C 248, 25.8.2011, p. 154.
[2] Position of the European Parliament of 13 September 2011 (not yet published in the Official Journal) and decision of the Council of 15 November 2011.
[3] OJ L 175, 5.7.1985, p. 40.
[4] See Annex VI, Part A.

ANNEX I

PROJECTS REFERRED TO IN ARTICLE 4(1)

1. Crude-oil refineries (excluding undertakings manufacturing only lubricants from crude oil) and installations for the gasification and liquefaction of 500 tonnes or more of coal or bituminous shale per day.

2. (a) Thermal power stations and other combustion installations with a heat output of 300 megawatts or more;

   (b) Nuclear power stations and other nuclear reactors including the dismantling or decommissioning of such power stations or reactors [1] (except research installations for the production and conversion of fissionable and fertile materials, whose maximum power does not exceed 1 kilowatt continuous thermal load).

3. (a) Installations for the reprocessing of irradiated nuclear fuel;

   (b) Installations designed:

      (i) for the production or enrichment of nuclear fuel;

      (ii) for the processing of irradiated nuclear fuel or high-level radioactive waste;

      (iii) for the final disposal of irradiated nuclear fuel;

      (iv) solely for the final disposal of radioactive waste;

      (v) solely for the storage (planned for more than 10 years) of irradiated nuclear fuels or radioactive waste in a different site than the production site.

4. (a) Integrated works for the initial smelting of cast iron and steel;

   (b) Installations for the production of non-ferrous crude metals from ore, concentrates or secondary raw materials by metallurgical, chemical or electrolytic processes.

5. Installations for the extraction of asbestos and for the processing and transformation of asbestos and products containing asbestos: for asbestos-cement products, with an annual production of more than 20 000 tonnes of finished products, for friction material, with an annual production of more than 50 tonnes of finished products, and for other uses of asbestos, utilisation of more than 200 tonnes per year.

6. Integrated chemical installations, i.e. those installations for the manufacture on an industrial scale of substances using chemical conversion processes, in which several units are juxtaposed and are functionally linked to one another and which are:

   (a) for the production of basic organic chemicals;

   (b) for the production of basic inorganic chemicals;

   (c) for the production of phosphorous-, nitrogen- or potassium-based fertilisers (simple or compound fertilisers);

   (d) for the production of basic plant health products and of biocides;

   (e) for the production of basic pharmaceutical products using a chemical or biological process;

   (f) for the production of explosives.

[1] Nuclear power stations and other nuclear reactors cease to be such an installation when all nuclear fuel and other radioactively contaminated elements have been removed permanently from the installation site.

7. (a) Construction of lines for long-distance railway traffic and of airports [1] with a basic runway length of 2 100 m or more;

   (b) Construction of motorways and express roads [2];

   (c) Construction of a new road of four or more lanes, or realignment and/or widening of an existing road of two lanes or less so as to provide four or more lanes, where such new road or realigned and/or widened section of road would be 10 km or more in a continuous length.

8. (a) Inland waterways and ports for inland-waterway traffic which permit the passage of vessels of over 1 350 tonnes;

   (b) Trading ports, piers for loading and unloading connected to land and outside ports (excluding ferry piers) which can take vessels of over 1 350 tonnes.

9. Waste disposal installations for the incineration, chemical treatment as defined in Annex I to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste [3] under heading D9, or landfill of hazardous waste, as defined in point 2 of Article 3 of that Directive.

10. Waste disposal installations for the incineration or chemical treatment as defined in Annex I to Directive 2008/98/EC under heading D9 of non-hazardous waste with a capacity exceeding 100 tonnes per day.

11. Groundwater abstraction or artificial groundwater recharge schemes where the annual volume of water abstracted or recharged is equivalent to or exceeds 10 million cubic metres.

12. (a) Works for the transfer of water resources between river basins where that transfer aims at preventing possible shortages of water and where the amount of water transferred exceeds 100 million cubic metres/year;

    (b) In all other cases, works for the transfer of water resources between river basins where the multi-annual average flow of the basin of abstraction exceeds 2 000 million cubic metres/year and where the amount of water transferred exceeds 5 % of that flow.

    In both cases transfers of piped drinking water are excluded.

13. Waste water treatment plants with a capacity exceeding 150 000 population equivalent as defined in point 6 of Article 2 of Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment [4].

14. Extraction of petroleum and natural gas for commercial purposes where the amount extracted exceeds 500 tonnes/day in the case of petroleum and 500 000 cubic metres/day in the case of gas.

15. Dams and other installations designed for the holding back or permanent storage of water, where a new or additional amount of water held back or stored exceeds 10 million cubic metres.

16. Pipelines with a diameter of more than 800 mm and a length of more than 40 km:

    (a) for the transport of gas, oil, chemicals;

    (b) for the transport of carbon dioxide (CO_2) streams for the purposes of geological storage, including associated booster stations.

17. Installations for the intensive rearing of poultry or pigs with more than:

    (a) 85 000 places for broilers, 60 000 places for hens;

    (b) 3 000 places for production pigs (over 30 kg); or

    (c) 900 places for sows.

---

[1] For the purposes of this Directive, 'airport' means an airport which complies with the definition in the 1944 Chicago Convention setting up the International Civil Aviation Organisation (Annex 14).
[2] For the purposes of this Directive, 'express road' means a road which complies with the definition in the European Agreement on Main International Traffic Arteries of 15 November 1975.
[3] OJ L 312, 22.11.2008, p. 3.
[4] OJ L 135, 30.5.1991, p. 40.

18. Industrial plants for the production of:

(a) pulp from timber or similar fibrous materials;

(b) paper and board with a production capacity exceeding 200 tonnes per day.

19. Quarries and open-cast mining where the surface of the site exceeds 25 hectares, or peat extraction, where the surface of the site exceeds 150 hectares.

20. Construction of overhead electrical power lines with a voltage of 220 kV or more and a length of more than 15 km.

21. Installations for storage of petroleum, petrochemical, or chemical products with a capacity of 200 000 tonnes or more.

22. Storage sites pursuant to Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide [1].

23. Installations for the capture of CO_2 streams for the purposes of geological storage pursuant to Directive 2009/31/EC from installations covered by this Annex, or where the total yearly capture of CO_2 is 1,5 megatonnes or more.

24. Any change to or extension of projects listed in this Annex where such a change or extension in itself meets the thresholds, if any, set out in this Annex.

[1] OJ L 140, 5.6.2009, p. 114.

ANNEXURE A2

EUROPEAN
COMMISSION

Brussels, 26.10.2012
SWD(2012) 355 final

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment
This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

{COM(2012) 628 final}
{SWD(2012) 354 final}

10. ANNEXES

10.1. Annex 1: Information on the EIA Directive

The EIA Directive has been in force since 1985 and applies to a wide range of defined public and private projects, which are described in its Annexes I and II:

- Mandatory EIA: All projects listed in Annex I are considered as having significant effects on the environment and require an EIA (e.g. long-distance railway lines, motorways and express roads, airports with a basic runway length ≥ 2100 m, installations for the disposal of hazardous waste, installations for the disposal of non-hazardous waste > 100 tonnes/day, waste water treatment plants > 150.000 p.e.).

- Discretion of Member States (screening): For projects listed in Annex II, the national authorities have to decide whether an EIA is needed. This is done by the 'screening procedure', which determines the effects of projects on the basis of thresholds/criteria or a case by case examination. However, the national authorities must take into account the criteria laid down in Annex III of the Directive. The projects listed in Annex II include for example urban development projects, flood-relief works, changes of Annex I and II existing projects, etc.

The Directive adopted in 1985 has been amended in 1997, in 2003 and in 2009:

- Directive 97/11/EC brings the Directive in line with the UN ECE Espoo Convention on EIA in a Transboundary Context. The Directive of 1997 widened the scope of the EIA Directive by increasing the types of projects covered, and the number of projects requiring mandatory EIA (Annex I). It also provided for new screening arrangements, including new screening criteria (at Annex III) for Annex II projects, and established minimum information requirements.

- Directive 2003/35/EC aligns the provisions on public participation with the Aarhus Convention on public participation in decision-making and access to justice in environmental matters.

- Directive 2009/31/EC amends Annexes I and II of the EIA Directive, by adding projects related to the transport, capture and storage of carbon dioxide (CO_2).

The initial Directive of 1985 and its three amendments have been codified by Directive 2011/92/EU of 13 December 2011.

The EIA procedure can be summarised as follows: the developer may request the competent authority to describe what should be covered by the EIA information to be provided by the developer (scoping stage); the developer must provide information on the environmental impact (EIA report – Annex IV); the environmental authorities and the public (and affected Member States) must be informed and consulted; the competent authority then makes a decision, taking into consideration the findings of the EIA report and the results of consultations. The public is informed of the decision afterwards and can challenge the decision before the courts.

European Commission

Interpretation of definitions of project categories of annex I and II of the EIA Directive

Annex I (5)

Annex I (5)

Installations for the extraction of asbestos and for the processing and transformation of asbestos and products containing asbestos: for asbestos-cement products, with an annual production of more than 20 000 tonnes of finished products, for friction material, with an annual production of more than 50 tonnes of finished products, and for other uses of asbestos, utilisation of more than 200 tonnes per year.

Asbestos has been banned throughout the European Union since 1 January 2005[37].

Annex I (6)

Integrated chemical installations, i.e. those installations for the manufacture on an industrial scale of substances using chemical conversion processes, in which several units are juxtaposed and are functionally linked to one another and which are:

(a) for the production of basic organic chemicals;

(b) for the production of basic inorganic chemicals;

(c) for the production of phosphorous-, nitrogen- or potassium-based fertilisers (simple or compound fertilisers);

(d) for the production of basic plant health products and of biocides;

(e) for the production of basic pharmaceutical products using a chemical or biological process;

(f) for the production of explosives.

The project category '*integrated chemical installations*' is divided into six sub-categories, which are nearly the same as those listed in point 4 of Annex I to the IED.[38] The list of organic and inorganic chemicals in the IED's Annex I could be used as a non-exhaustive list for the purposes of the EIA Directive as well:

Organic chemicals include: (a) simple hydrocarbons (linear or cyclic, saturated or unsaturated, aliphatic or aromatic); (b) oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters, acetates, ethers, peroxides,

[37] Commission Directive 1999/77/EC of 26 July 1999 adapting to technical progress for the sixth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos).

[38] It should be noted that the EIA Directive only covers integrated installations, which is a sub-set of that covered by IED. In addition, there are some differences in the descriptions. Firstly, while the EIA Directive refers to *basic* organic and inorganic chemicals, the IED omits the term *basic* although this was merely for clarification. Secondly, point 6(d) of Annex I to the EIA Directive refers to *production of plant health products and of biocides*, while the IED refers to *Production of plant protection product or of biocides* (point 4.4, Annex I).

Annex I (6)

epoxy resins; (c) sulphurous hydrocarbons; (d) nitrogenous hydrocarbons such as amines, amides, nitrous compounds, nitro compounds or nitrate compounds, nitriles, cyanates, isocyanates; (e) phosphorus-containing hydrocarbons; (f) halogenic hydrocarbons; (g) organometallic compounds; (h) plastic materials (polymers, synthetic fibres and cellulose-based fibres); (i) synthetic rubbers; (j) dyes and pigments; (k) surface-active agents and surfactants.

Inorganic chemicals include: (a) gases, such as ammonia, chlorine or hydrogen chloride, fluorine or hydrogen fluoride, carbon oxides, sulphur compounds, nitrogen oxides, hydrogen, sulphur dioxide, carbonyl chloride; (b) acids, such as chromic acid, hydrofluoric acid, phosphoric acid, nitric acid, hydrochloric acid, sulphuric acid, oleum, sulphurous acids; (c) bases, such as ammonium hydroxide, potassium hydroxide, sodium hydroxide; (d) salts, such as ammonium chloride, potassium chlorate, potassium carbonate, sodium carbonate, perborate, silver nitrate; (e) non-metals, metal oxides or other inorganic compounds such as calcium carbide, silicon carbide.

'Integrated', 'juxtaposed' and 'functionally linked'

The first guidance on 'integrated', 'juxtaposed' and 'functionally linked' was provided by case law (see Case C-133/94, *Commission v Belgium*). The Court ruled that '*whether a chemical installation is integrated does not depend upon its processing capacity or on the type of chemical substance processed in it but on the existence of interlinked production units constituting in terms of their operation a single production unit*'. It should be noted that this definition applied before Annex I(6) was amended by Directive 97/11/EC.[39]

Therefore, the basis for interpretation of 'integration' would be that various units are present and a linkage between various parts of a chemical plant exists. The functional linkage will be primarily via a process pathway, i.e. the various units of the installation serve a common purpose by producing intermediates or input material (precursors, auxiliary agents etc.) for other units. The various elements of the plant will therefore contribute to producing a finished product (or products), although it is possible that part of the intermediates or input materials produced in the plant will also be placed on the market. Additionally, there may be infrastructural linkage (for example, for energy purposes), but this alone does not constitute a functional linkage.

The term 'juxtaposed' commonly means 'placed side by side' or 'placed next to one another'. However, given the broad purpose of the Directive, there does not appear to be a requirement for any particular unit to be placed *immediately* next to another, since precursors may be produced on a different part of the site, and transferred by

[39] Annex I(6) to Directive 85/337/EEC prior to amendments referred to *'Integrated chemical installations'.*

Annex I (6)

pipeline, conveyor or other forms of transfer to a finishing or process area. Such obviously directly associated activities have a functional connection with the other activities carried out on that site and could have environmental effects.

'Manufacture on an industrial scale'

Annex I(6) contains no quantitative capacity thresholds but only a reference to 'manufacture on an industrial scale'.

Annex I to the IED provides that the Commission is to establish guidance on the interpretation of the term 'industrial scale' regarding the description of chemical industry activities described in the Annex.

'Chemical conversion processes'

Annex I(6) makes reference to manufacture on an industrial scale using 'chemical conversion processes'. 'Chemical conversion processes' imply that transformation by one or several chemical reactions takes place during the production process. This also holds for a biotechnological or biological process that is mostly associated with a chemical conversion (e.g. fermentation). An activity involving only physical processing (for instance, simple blending or mixing of substances that do not chemically react, dewatering, dilution, repackaging of acids/bases) would not be covered.

In comparison, in Annex I to the IED, point 4 defines 'production' within the chemical industry as *the production on an industrial scale by chemical or biological processing of substances or groups of substances* listed under that point.

Use of the term 'basic'

The term 'basic'[40] does not mean only those chemicals requiring further processing but also certain final (but still basic) chemical products (for instance, synthetic rubbers, dyes and pigments, polymers and synthetic fibres) that can undergo further (non-chemical) processing. The production of a mixture of chemicals could also be considered as the production of 'basic' chemicals. For instance, biodiesel composed largely of a mixture of esters would fall under the term 'basic organic chemicals' since this relates to the production of esters.

The term would however not cover final products that cannot be considered to be 'chemical products'. For instance, the production of tyres from rubber with other ingredients involves some form of chemical processing without producing a 'basic chemical product'.

[40] It should be noted that the term 'basic' is no longer used in the activity descriptions under point 4 of Annex I to Directive 2010/75/EU on industrial emissions.

EPA/600/R-12/043F | September 2013 | www.epa.gov

ANNEXURE A4

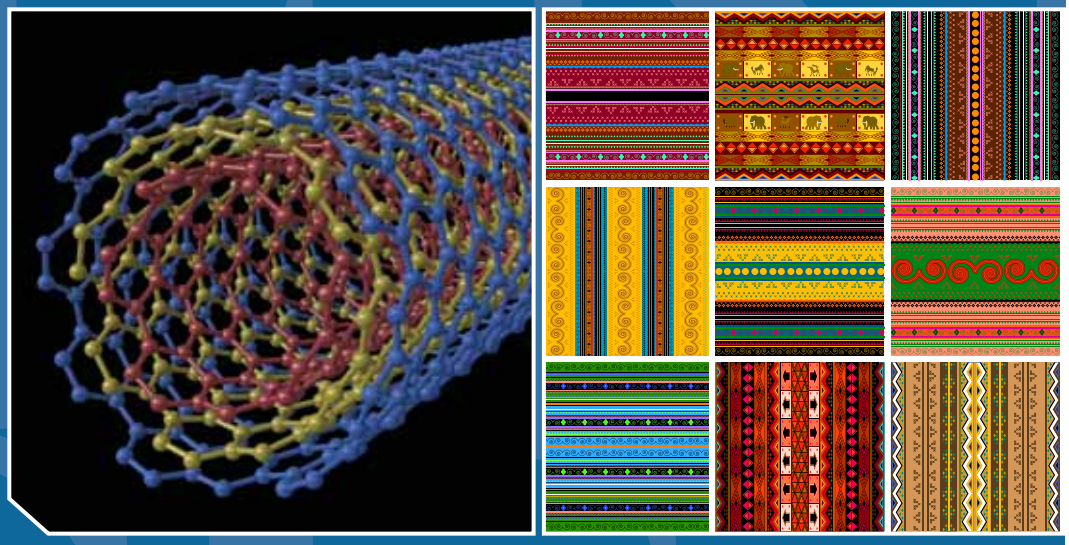
16

United States
Environmental Protection
Agency

Comprehensive Environmental Assessment Applied to:

Multiwalled Carbon Nanotube Flame-Retardant Coatings in Upholstery Textiles—

A Case Study Presenting Priority Research Gaps for Future Risk Assessments



United States Environmental Protection Agency; Office of Research and Development
National Center for Environmental Assessment

Executive Summary

Chapter 1: Introduction to this Document

Background

As part of an ongoing effort to identify research needs and data gaps in assessing the broad environmental implications of nanomaterials, this case study focuses on a specific nanomaterial in a particular application: multiwalled carbon nanotubes (MWCNTs) in flame-retardant coatings applied to upholstery textiles. The selection of this specific nanomaterial and particular application was made with input from representatives across the U.S. Environmental Protection Agency (EPA) and was based in part on its relevance to EPA programmatic interests and the similarity in the potential for release and exposure over the product life cycle compared to conventional flame-retardant materials that are being phased out of use.

Like previous case studies of nanoscale titanium dioxide and nanoscale silver, this case study is built on the comprehensive environmental assessment (CEA) approach, which is both a framework and a process. The CEA framework (Figure 1-1) starts with the inception of a material and encompasses environmental fate, exposure-dose, and impacts associated with that material. The framework also considers differences in environmental media and the physical, chemical, biological, and social conditions in which the material occurs. Here, the framework is used to organize information about MWCNTs in the case study systematically. This information does not represent a completed or even preliminary risk assessment; rather, it is intended to inform research planning. The External Review Draft of the document provided a basis for identifying and prioritizing data gaps and research needs for MWCNTs and other nanomaterial assessments as part of the CEA process (Figure 1-2). Specifically, a group of expert stakeholders representing diverse technical (e.g., human health effects, ecological effects, material characterization) and sector (e.g., industry, academia, government) perspectives engaged in a structured, collective judgment workshop process such that each individual had equal input in identifying research priorities. To facilitate the identification of key research gaps related to assessing MWCNTs in this application, the External Review Draft case study provided a comparative perspective by also presenting information on a traditional flame retardant, decabromodiphenyl ether (decaBDE). The prioritized research gaps that emerged are intended to inform decision-makers in the EPA and the broader scientific community in developing research agendas that support future risk assessment and risk management goals for MWCNTs. Strategic research planning focused on supporting future risk assessment and

management is responsive to guidance from the National Research Council and others to place more emphasis on problem formulation and the identification of broader potential impacts of materials under evaluation in the risk assessment [see Chapter 6; (U.S.GAO, 2013; NRC, 2011, 2009)]. Moreover, identifying research priorities for future risk assessment and management can help to ensure that the effects of resources allocated to research are maximized (i.e., focused on the most pressing data gaps).

The Priority Research Areas that were identified for MWCNTs are the primary focus of this revised document, with information on decaBDE that supported identifying the priorities in the previous draft (U.S. EPA, 2012b) presented primarily in Appendix H. Background information on decaBDE, however, is provided in Chapter 1 to give the necessary context for reviewing the research priorities identified for MWCNTs. In addition, text boxes with the title "DecaBDE Can Inform MWCNT Assessment" are provided throughout the document to succinctly note how information on the conventional material might inform research planning for MWCNTs. Information on MWCNTs that pertains to areas that were not prioritized for research is now located in Appendix G. Input on the External Review Draft case study from public and expert stakeholders also is highlighted throughout the document and is recorded in Appendix I.

Given the purpose of the document, this case study does not purport to be a comprehensive literature review; rather, available sources were incorporated specifically to support prioritizing and subsequently planning research, as described above. As this case study involves an emerging technology, some information, particularly regarding background or general concepts, was occasionally obtained from non-peer-reviewed sources to supplement the published literature available. The most recent literature search for this case study was conducted in May 2012 using specific criteria relevant to MWCNTs in flame retardants. Additional targeted literature searches were conducted on November 13, 2012, using search terms specific to topic areas identified in public and expert comments. Specific references suggested by experts through an independent Letter Peer Review were then incorporated into the document in May 2013.

Introduction to decaBDE and MWCNT flame-retardant textiles

Production and importation of decaBDE are currently being phased out in the United States as a result of voluntary commitments within the industry and EPA actions in response to concerns regarding potential human health and ecological impacts. As a result, a range of alternative flame-retardant technologies, including nanotechnologies, is being evaluated as potential replacements for this extensively used material. This document presents information on a potential alternative flame-retardant technology, MWCNTs, in the context of the research priorities that could support future assessments of this product. The primary purpose of this document is to inform research planning efforts for MWCNTs

across the scientific community. In doing so, the document supports a key objective of the CEA approach; to link research, risk assessment, and risk management efforts iteratively.

In developing research plans for MWCNTs, understanding the considerations involved in their potential use in flame-retardant textiles is informative. Many manufacturers incorporated flame-retardant materials into textiles to comply with state, federal, and industry fire-safety standards (i.e., certain flame test performance criteria that must be met). Once applied, flame retardants act to inhibit the combustion process through a variety of physical or chemical means (e.g., producing inert gases that dilute the oxygen supply available to the flame, producing protective char barriers) (Section 1.2).

Both decaBDE and MWCNTs can be mixed with binding agents and applied as coatings to increase the flame resistance of upholstery textiles. In this application, the two materials are both referred to as barrier technologies because they exhibit similar mechanisms of flame-retardant action: decaBDE forms a protective char barrier and MWCNTs form a network floccules layer (i.e., network of loosely bound MWCNT bundles). The similarity in potential applications for decaBDE and MWCNTs was a primary reason for including the comparison of the two materials as flame-retardant coatings in upholstery textiles in the External Review Draft of the case study, as the comparison informed the identification of data gaps related to assessing possible risks and benefits associated with MWCNTs. Moreover, the comparison of these materials highlighted MWCNT- and nano-specific factors that might influence future research directions for nanomaterials and nanoenabled products. For example, unlike with decaBDE, the physicochemical properties of MWCNTs are often intentionally altered during synthesis; thus MWCNTs are not a single material with a defined set of characteristics, but rather a variety of materials—often present as mixtures—with vastly different physicochemical characteristics. Such variation in the physicochemical characteristics of MWCNTs presents challenges in describing the releases, behavior, and effects of exposure to MWCNTs as a class of materials (Section 1.3). Importantly, MWCNTs likely will be used in combination with other flame-retardant materials to provide sufficient efficacy for the standards noted above (Section 1.2). In addition to introducing greater variability in MWCNT behavior, exposure, and effects, the use of MWCNTs in combination with other materials raises important implications for the potential use of MWCNTs in this application (Additional Information Highlight Box 3).

Chapter 2: Product Life Cycle

Little information is available on the commercial production and use of MWCNT flame-retardant coatings, as few commercial-scale products currently exist. The manufacturing stages of MWCNT flame-retardant textile coatings (Section 2.2), along with the use (Section 2.4) and reuse/recycling/end-of life

stages (Section 2.5), were identified as Priority Research Areas for upholstery textiles treated with MWCNT flame retardants.

Based on the available data, releases of MWCNTs to the environment are expected to occur throughout the life cycle of MWCNT flame-retardant upholstery textiles. The projected increase in MWCNT production likely will result in increased environmental releases of MWCNTs from flame-retardant textiles or other MWCNT products. Most MWCNTs released in the manufacturing stages are anticipated to be in the free or bundled form (Footnote 13 in Chapter 2 explains this terminology), while most releases later in the life cycle are anticipated to be in the polymer or textile matrix-bound form. Upholstery textile products are expected to have a long lifespan and likely will be disposed of in municipal landfills or incineration facilities.

Air and water releases of MWCNTs during manufacturing are expected to occur based on the activities performed in manufacturing stages of the product life cycle. Although release is particularly likely during mixing, handling, and equipment cleaning, releases are expected to be fairly well controlled when proper ventilation and environmental controls are in place. Air releases of MWCNTs have been measured during material synthesis but no data are available regarding release to water during manufacturing. Additionally, MWCNTs typically require purification and functionalization, which also could result in releases due to chemical and physical processing methods (Section 2.2). Activities like textile and furniture processing might take place outside of closed systems and could result in environmental releases of MWCNTs. Abrasion, washing, unintended use, and accidental exposure to high heat or fire during the use stage could result in releases of MWCNTs (Sections 2.4 and 2.5).

No data are currently available on the volume or potential release of MWCNTs in the use stage of the flame-retardant upholstery textile product life cycle. Based on decaBDE data, however, the potential for release during this stage of the product life cycle could be relatively high. Similarly, no data currently exist on the volume or potential release of MWCNTs in upholstery textiles at end of life. Nevertheless, the physical and chemical processes (e.g., shredding, milling, chemical treatment) used to recycle textiles also could lead to releases of MWCNTs. Air releases from land-filling of MWCNT flame-retardant upholstery also could occur due to mixing and compacting. In addition, release in leachate from landfills is possible if the product or polymer matrix degrades. Although incineration at end of life presents the potential for airborne release of MWCNTs and by-products, preliminary experimental data suggest that MWCNTs will not be released to the environment when exposed to the sufficiently high temperatures of municipal incinerators (Sections 2.4 and 2.5). Incomplete incineration during other stages of the product life cycle, however, is one of the most likely airborne release scenarios for CNT textile coatings.

Chapter 3: Transport, Transformation, and Fate

Although MWCNTs are incorporated into polymer matrices after the flame-retardant production stage, little information exists that describes the environmental behavior of these polymer matrices. As a result, Chapter 3 focuses on the transport, transformation, and fate of MWCNTs and not the polymer matrices in which they are incorporated. Environmental transport, transformation, and fate of MWCNTs in air, wastewater, and sediment were identified as Priority Research Areas. The environmental behavior of MWCNTs is dictated by their physical and chemical properties—surface area, surface chemistry, morphology (shape), solubility (Footnote 16 in Chapter 2 explains this terminology), presence or absence of functionalization and surface coatings (e.g., engineered coatings or natural organic matter), and hydrophobicity. The nanostructured morphology, small size, and high surface area-to-volume ratio of MWCNTs can enhance chemical reactivity and propensity of MWCNTs to form bundles; however, single MWCNTs, as compared to bundles, will differ in their behavior in the environment (Section 3.1).

Recent literature regarding the behavior of airborne MWCNTs is extremely limited, and dominant fate, transport, and transformation processes for MWCNTs in indoor and outdoor air are unknown. In aqueous media, such as wastewater, the hydrophobicity, and van der Waals interactions of pure MWCNTs suggest they will bundle together or sorb to particles and be removed during the sewage treatment process, or settle out into sediment in receiving water bodies. Physicochemical characteristics of the MWCNTs and environmental conditions, however, can alter this behavior. For example, the presence of dissolved organic matter has been shown to debundle MWCNTs causing to them to remain in solution. Similarly, surface coatings can affect the sorption behavior of MWCNTs in these systems and influence their mobility, dispersion, and bioavailability in environmental media (Sections 3.2, 3.3, and 3.4).

Scientists have demonstrated the use of simple, deterministic models and more complex probabilistic models to simulate movement of carbon nanotubes through, and predict environmental concentrations in, environmental compartments. Differences in modeling approaches, model scale, and model input data make comparisons across models for predicting environmental concentrations of CNTs difficult. Nevertheless, a recent life-cycle-based analysis predicted the impacts of CNT synthesis in aquatic systems by using output data from a single model of environmental concentrations (Section 3.5).

Chapter 4: Exposure-Dose

Several analytical challenges for nanomaterials combined with the lack of historical use of MWCNTs in consumer products have so far prevented MWCNTs from being detected in ambient media, which could inform decisions related to potential exposures in human and ecological populations (Section 4.1). Human exposures to MWCNTs released throughout the flame-retardant textile coating life cycle are

expected to differ for workers, consumers, and the general public. Based on available information, occupational and consumer exposures were identified as Priority Research Areas in the CEA collective judgment workshop process for MWCNTs. Workers can be exposed to various forms of MWCNTs (e.g., adsorbed to dust, as part of the polymer or textile matrix) via inhalation and ingestion of, and dermal contact with, these substances during manufacturing, storage and distribution, and end-of-life activities. In the workplace, the inhalation route is expected to represent the greatest potential for exposures, and MWCNTs are expected to be in the particulate phase when inhaled. Little is reported about consumer exposures to MWCNTs, especially those incorporated into flame-retardant textiles. Yet, based on activities expected to occur during use, repurposing, or reuse of upholstered products, consumers might be exposed to MWCNTs during each of these points in the product life cycle. The MWCNTs released from finished products also are expected to be in particulate form, generally adsorbed to dust or constituents of the polymer or textile matrix. The primary route of exposure (i.e., inhalation, ingestion, or dermal) for consumers is unknown.

Developing exposure standards, guidelines, or recommendations for MWCNTs is complicated by the heterogeneity in MWCNT configurations and challenges measuring MWCNTs in occupational or environmental settings. The National Institute for Occupational Safety and Health (NIOSH) established a recommended exposure limit for elemental carbon, and several other occupational exposure limits have been proposed by industry and international agencies (Section 4.2.5). In general, MWCNTs appear to be biopersistent and might remain in the lung for several months after inhalation. Limited studies show that, after oral exposure, most ingested MWCNTs are eliminated with no detectable metabolism or transport into the blood. Distribution to the liver, lungs, and spleen, however, has been reported following intravenous exposure (Section 4.2). Notably, the bioavailability, and thus dose, of MWCNTs likely will be based on whether they are bound in a textile matrix, bundled, or free (Footnote 13 in Chapter 2 explains this terminology).

No evidence is currently available to determine whether portions of the population might experience higher exposure levels to MWCNTs compared to the general population; however, the activity of children and workers might increase total exposure levels of MWCNTs relative to the general population (Section 4.2).

Exposure and dose in ecological populations were not deemed Priority Research Areas for MWCNTs in the CEA collective judgment workshop process, and thus information on these areas is now located in Appendix G and Appendix H for MWCNTs and decaBDE, respectively. The anticipated increase in MWCNT production (Section 2.2.2) along with increases in potential applications of the material could lead to an increase in the number and type of exposures experienced by workers,

consumers, and ecological populations. These changes are expected to increase aggregate and cumulative exposures to different formulations of MWCNTs, transformation products, and by-products.

Chapter 5: Potential Human Health, Ecological, and Other Impacts

Expert stakeholders participating in the CEA collective judgment workshop process identified human health impacts as a Priority Research Area for MWCNTs. Toxicology studies conducted on animals are the only identified data on human health impacts of MWCNTs because no human data on effects of MWCNT exposure exist. All routes of exposure were examined in this case study because each route (dermal, inhalation, and oral) offers potential for human exposures (Section 5.1). Toxicological effects from MWCNT exposure in animal models have been evaluated predominantly after dermal and inhalation exposures, rather than after oral exposure. Effects were generally localized and included irritation (skin and ocular), sensitization (respiratory), and inflammation (respiratory). In addition, MWCNTs altered immunological function after exposure via inhalation for 14 days or via a single intranasal injection. The carcinogenicity of MWCNTs following inhalation exposure has not been investigated; however, several studies using methods such as instillation indicate that some types of MWCNTs behave like asbestos, potentially inducing mesotheliomas, and might be more toxic than asbestos (Section 5.1).

Expert stakeholders identified impacts in aquatic, but not terrestrial, biota as a Priority Research Area. Considerations for the ecological impact of MWCNTs include the toxicity toward different species, types of effects, and potential for bioaccumulation and biomagnification. More than 20 studies have investigated the effects of MWCNTs on aquatic species or aquatic systems; those studies indicate low acute toxicity potential, with the effect level varying based on size and functionalization properties of the MWCNTs. Chronic studies show that MWCNTs can elicit immune responses and produce developmental impacts (Section 5.2).

Other impacts, including economic or societal effects and alterations in environmental resources, were identified as a Priority Research Area by expert stakeholders. No empirical data exist relating MWCNTs to other impacts, but the background literature on processes involved in manufacturing similar materials (e.g., carbon nanofibers, single-walled carbon nanotubes) provides some basis for concern regarding potential impacts of MWCNTs on energy demand, resource depletion, climate change, and economics. These related studies provide a plausible foundation for suggesting that MWCNT manufacturing can be an energy-intensive process potentially causing the depletion of nonrenewable natural resources like fossil fuels, and that the synthesis of MWCNTs can result in emissions of other compounds causing adverse environmental effects (e.g., volatile organic compounds; Section 5.3).

Chapter 6: Identifying and Prioritizing Research Needs to Support Risk Assessment and Risk Management

The External Review Draft of this document served as the foundation from which expert stakeholders participating in the CEA process could identify key data gaps and determine research priorities. The information presented in this revised document focuses on those priorities to inform ongoing research planning for nanotechnology in the general scientific community and at EPA. Results of these research efforts could subsequently support future assessments and risk management efforts for MWCNTs or other nanomaterials. Future evaluations of nanoenabled products, such as MWCNT in flame-retardant textile coatings, could involve the consideration of risk-related trade-offs, for example, thyroid health effects versus pulmonary health effects and environmental justice considerations versus energy costs. This document therefore strives to inform research planning efforts that would support conducting risk assessments that can inform risk management decisions about such trade-offs.

The research priorities discussed in the case study were identified by a group of diverse expert stakeholders independently rating areas of the CEA framework based on two factors:

- Importance: how important an area is to consider in risk assessments of MWCNTs;
- Confidence: the availability and utility of current data to support risk management decisions for MWCNTs.

For those areas they identified as “Important” to consider in future risk assessments of MWCNTs, stakeholders were asked to rate the relative importance and confidence in data related to the relationship of the area with risk factors that might be considered in risk assessment or risk management efforts for the area. Areas that experts most commonly identified as being of high importance to risk assessment, and were not confident in the data to support risk management decisions, are considered high priorities for research. In contrast, areas rated as of high importance and for which experts had confidence in the data might be of interest to decision-makers for evaluating risk management options for MWCNTs.

Most of the prioritized CEA framework areas were considered research priorities, including release rates across the product life cycle; persistence and bioavailability in air, wastewater, or sediment, and inhalation exposure in workers and consumers. Other areas identified as high Priority Research Areas include absorption, metabolism, and excretion in humans, as well as impacts on human health, aquatic biota, and other considerations (i.e., economic, societal, environmental resources). For a subset of these areas, experts identified potential risk management decisions in the context of an example risk scenario for that area and noted the type of assessment(s) that could inform those decisions. Specific research questions to support such assessments also were identified, along with estimates of the financial and time resources to carry out the research. Risk management decisions generally centered on choosing

appropriate control technologies or personal protective equipment, modifications to MWCNTs (e.g., reducing residence time in air by increasing aggregation potential), or limits on production and use of the materials. Assessments to inform these and other types of risk management efforts included human health risk assessments, cost benefit analyses, and life cycle assessments. Research areas to support such assessments can be grouped into five general themes: (1) the influence of MWCNT characteristics on release from the product matrix; (2) the influence of MWCNT characteristics and the product matrix both on environmental transport and transformation, and on absorption across biological barriers (e.g., gastrointestinal tract); (3) development of analytical methods or tools to detect MWCNTs in complex matrices and measure exposures; (4) human health impacts of MWCNTs and co-factors (e.g., solvents) after acute and chronic exposures; and (5) improving public engagement in and understanding of potential benefits and risks of nanotechnology.

The connection of specific questions within Priority Research Areas to the assessments and risk management decisions they would subsequently support demonstrates the focus within the CEA approach on linking communication across the continuum of research, risk assessment, and risk management. Moreover, the specific questions are intended to provide more concrete support for strategic research planning that informs future decision-making about MWCNTs.

ANNEXURE A5
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NANOMATERIAL CASE STUDY WORKSHOP:

DEVELOPING A COMPREHENSIVE ENVIRONMENTAL ASSESSMENT RESEARCH STRATEGY FOR NANOSCALE SILVER

JANUARY 4–7, 2011
RESEARCH TRIANGLE PARK, NORTH CAROLINA

WORKSHOP REPORT

PREPARED FOR EPA/NCEA

DECEMBER 2011

PREPARED BY ICF INTERNATIONAL UNDER
EPA CONTRACT NUMBER EP-C-09-009,
WORK ASSIGNMENT NUMBER 2-12

1. Workshop Objectives and Design

Engineered nanoscale materials (nanomaterials) are conventionally described as having at least one dimension between 1 and 100 nanometers (nm) and possessing unusual, if not unique, properties that arise from their small size. Like all technological developments, nanomaterials offer the potential for both benefits and risks. Given the emerging state of nanotechnology, however, much remains to be learned about the characteristics and effects of nanomaterials before such assessments can be completed.

In its 2007 Nanotechnology White Paper (2007), the U.S. Environmental Protection Agency (EPA) included the recommendations shown in the text box at the right regarding the risk assessment of nanomaterials. The approach the National Center for Environmental Assessment (NCEA), in EPA's Office of Research and Development, adopted is to draft a case study that details the information currently available to complete a comprehensive environmental assessment (CEA) for a selected nanomaterial in a specific application. The CEA approach consists of both a framework and a process. The CEA framework provides a structure to develop a comprehensive view of what is known about the nanomaterial application beginning with the product life cycle; progressing to its environmental fate and transport, exposure-dose in ecological and human populations, and finally, ending with its human health, ecological, and other (aesthetic, climate, energy, sustainability, etc.) impacts. This approach enables identification of gaps in our knowledge and corresponding research topics that could help support a CEA of the nanomaterial. Compiling the information on what is known about the nanomaterial is the first step in the CEA process (Figure 1-1). Next, a collective judgment process is used to evaluate and then prioritize this information. Collective judgment, as has been applied in the CEA process to date, refers to a formal, structured procedure that enables a diverse group of individuals to be heard individually and represented in a transparent record of the collectively reached outcomes. In turn, it supports an essential feature of CEA: the inclusion of diverse technical and stakeholder perspectives to ensure that a holistic evaluation is achieved (U.S. EPA, 2010c).

Recommendations to Address Overarching Risk Assessment Needs – Case Study

One way to examine how a nanomaterial assessment would fit within EPA's overall risk assessment paradigm is to conduct a case study based on publicly available information on one or several intentionally produced nanomaterials. … From such case studies and other information, information gaps may be identified, which can then be used to map areas of research that are directly affiliated with the risk assessment process. This has been done in the past with research on airborne particulate matter.

Additionally, a series of workshops involving a substantial number of experts from several disciplines should be held to use available information and principles in identifying data gaps and research needs that will have to be met to carry out exposure, hazard, and risk assessments.

2007 Nanotechnology White Paper (2007) (p. 89)

The outcomes of the workshops—prioritized information gaps and risk tradeoffs—will be used in developing and refining a long-term research strategy to assess potential human health and ecological risks of nanomaterials and to manage associated risks of specific nanomaterials.

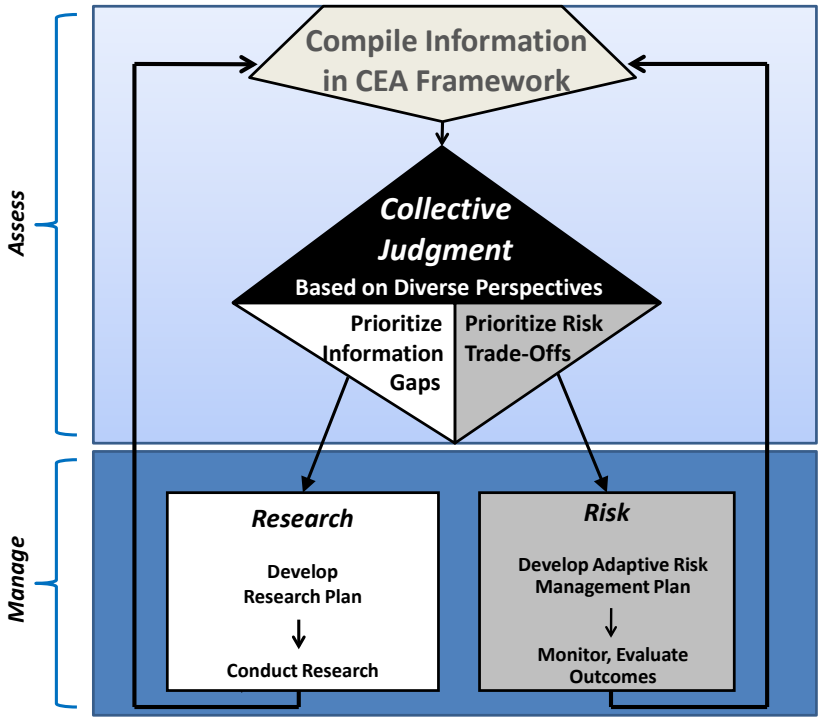


Figure 1-1. Steps in the CEA process.

The first workshop in this series, "Nanomaterial Case Study Workshop: Developing a Comprehensive Environmental Assessment Research Strategy for Nanoscale Titanium Dioxide," was held in 2009 and focused on EPA's *Nanomaterial Case Studies: Nanoscale Titanium Dioxide in Water Treatment and in Topical Sunscreen* (U.S. EPA, 2010a). The outcomes from that workshop are reported in EPA's *Workshop Summary for the EPA Board of Scientific Counselors* (U.S. EPA, 2010c). NCEA sponsored its second "Nanomaterial Case Study Workshop: Developing a Comprehensive Environmental Assessment Research Strategy for Nanoscale Silver" January 4–7, 2011, in Research Triangle Park, North Carolina. The starting point for the workshop was EPA's external review draft of *Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray* (U.S. EPA, 2010b).

Both workshops used nominal group technique (NGT) as the collective judgment tool to facilitate the discussion and prioritization of information needs among the group of diverse participants. NGT is a structured process whereby several individuals (nominally a group) are convened to identify and rank a number of choices and each person is afforded an equal opportunity to offer his or her view(s) about which choices are highest priority. More information regarding how this technique was put to use is provided in Section 1.4.2.

The most recent workshop on nanoscale silver improved on the format based on the lessons learned from the first workshop and the input of EPA's Board of Scientific Counselors. Fewer participants were selected for the 2011 workshop, reducing overall costs. In addition, one group of participants was used in the second workshop, instead of two, eliminating time required to consolidate the priority research needs they identified. The time saved was allotted to breakout group discussions, allowing for the participants to report on the top 13 rather than top 8 consolidated research needs. In fact, for the nanosilver workshop, less consolidation was encouraged, which resulted in more, and more distinct, categories of research needs.

An important point to emphasize is that none of the nanomaterial case study documents and workshops are intended to be ends in and of themselves, even though intrinsically they might have value or be of interest. They are primarily viewed as initial steps in the development and refinement of a long-range research strategy to support CEAs of selected nanomaterials. Full implementation of such a strategy requires preparing additional nanomaterial case studies, and the process is expected to evolve, reflecting adjustments and modifications as additional nanomaterials are considered and new information becomes available.

This report describes the outcomes of the 2011 nano-Ag workshop. Figure 1-2 illustrates the workshop design. Refer to the 2010 *Workshop Summary for the EPA Board of Scientific Counselors* for more information on the approach used in developing the case studies, the rationale in designing the workshops, and the outcomes of the 2009 workshop (U.S. EPA, 2010c).

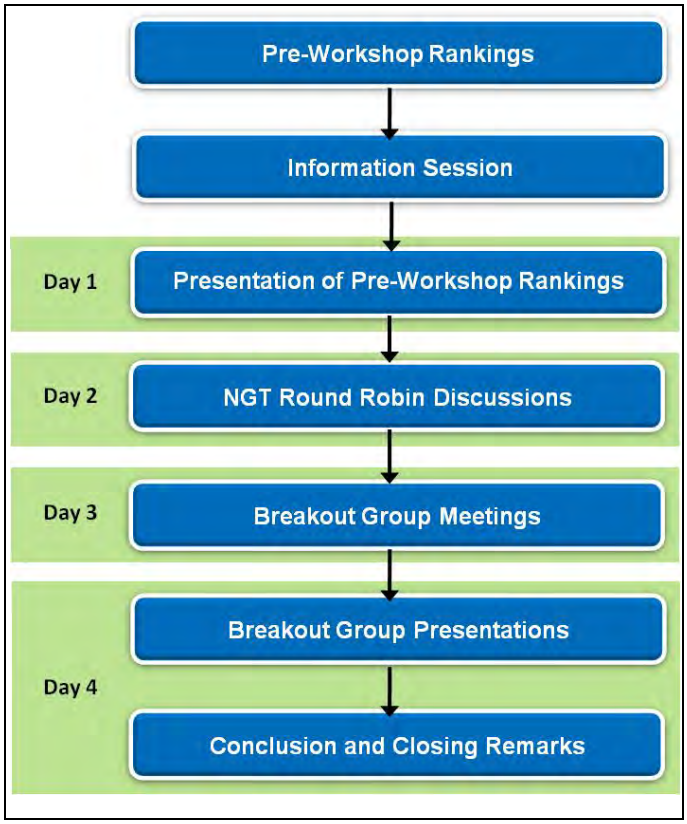


Figure 1-2. Nano-Ag Workshop Design.

1.1. Workshop Objectives

The goal of this workshop was to prioritize responses to the following question:

> What research or information is most needed to conduct a comprehensive environmental assessment of nano-Ag used in disinfectant spray?

As discussed in Section 1.4.2, participants were guided through the NGT process, which enabled them to identify and rank issues in response to the above question using their independent judgments and the collective judgment of the group. The sections that follow describe the selection of participants, pre-workshop activities, implementation of NGT for the workshop, and structure of the breakout group reports.

1.2. Selection of Participants

Securing a multidisciplinary and multistakeholder set of workshop participants involved several steps, with a goal of achieving a diverse array of technical and stakeholder perspectives to yield insights that would be useful in defining what is essential to complete a CEA of this emerging nanotechnology. EPA retained ICF International to help organize and facilitate the workshop.

First, a list of candidate participants was developed based on information EPA provided, Internet searches, and other investigation. From available biographical information, participants were assigned to categories based on their sector (academia, consulting, NGO, etc.) and subject matter expertise. Considerable attention was given to achieving, as much as possible, a balanced representation across sectors and areas of expertise.

A target number of 25 participants was set. Because the 49 participants in the 2009 nano-TiO_2 workshop, working in two NGT groups, independently identified similar research priorities, EPA decided that 25 participants, working in one NGT group were sufficient to accomplish the 2011 workshop goals.

To ensure a final total of 25 participants, 30 potential participants were initially invited. When a potential participant declined, an alternate was identified to maintain a balanced distribution of disciplines and stakeholders. Ultimately, 23 participants, listed in Table 1–1, attended the workshop. Table 1-2 lists the sector representation, and Section 4.2 presents the biographical sketches each participant provided.

Table 1–1. Workshop Participant Names and Affiliations

Participant	Affiliation	Sector
Mary Boudreau	U.S. Food and Drug Administration	Government
Mark Chappell	U.S. Army Engineer Research and Development Center	Government
Hongda Chen	USDA National Institute of Food and Agriculture	Government
Mary Jane Cunningham	Nanomics BioSciences	Industry
James Delattre	NanoHorizons	Industry
David Ensor	RTI International	Consulting
Michael Hansen	Consumer's Union	NGO, Labor, Journalism
Carol Henry	Independent Consultant	Consulting
Matthew Hull	NanoSafe Inc.	Industry
Ian Illuminato	Friends of the Earth	NGO, Labor, Journalism
Larry Kapustka	LK Consultancy	Consulting
Bojeong Kim	Virginia Tech University	Academia
Kristen Kulinowski	Rice University CBEN	Academia
Debbie Lander	DuPont	Industry
Paul Lioy	EOHSI / Rutgers University – UMDNJ-RWJMS	Academia
Brian O'Connor	FPInnovations – PAPRICAN	Industry
Maria Powell	Nanotechnology Citizen Engagement Organization	NGO, Labor, Journalism
Gurumurthy Ramachandran	University of Minnesota	Academia
Christie Sayes	Texas A&M University	Academia
Maria Sepulveda	Purdue University	Academia
Brian Strohmeier	RJ Lee Group	Consulting
Michael Tolocka	University of North Carolina – Chapel Hill	Academia
Dik van de Meent	RIVM Laboratory for Ecological Risk Assessment	Government

Table 1–2. Participant Sector Representation

Sector	Total	Participants
Academia	7	B, F, L, O, U, V, W
Industry	5	D, H, R, S, T
NGO, Labor, Journalism	3	A, K, N
Consulting	4	C, F, G, M
Government	4	I, J, P, O
Total	23	--

Upon acceptance of the invitation, each participant received a conflict of interest disclosure form to complete; no conflicts were identified. Generally, a written agreement was executed with each nonfederal-government participant for reimbursement of travel expenses and payment of an honorarium of $2,000 for services. A purchase order agreement and honorarium were used to help ensure that participants would understand that a commitment of their time and attention was expected and that their services were not being offered gratis.

1.3. Pre-Workshop Review and Rankings

Confirmed participants were asked to review the nano-Ag case study document in advance of the workshop and, using an Excel-based form, submit their preliminary rankings of research questions listed in the case study. They also were invited to submit review comments on the case study, to be considered in revising the case study document prior to final publication. The objective of having the participants rank the questions and review the draft case study document prior to the workshop was both to help ensure that participants actively read the document and to prepare them to provide final ranking of the issues in priority order. Essentially, this pre-workshop exercise was intended to substitute for the brainstorming aspect of NGT (Van de Ven and Delbecq, 1972).

Participants were asked to determine their rankings of research questions by selecting: (1) the 10 most important questions identified in the draft case study document in rank order from 1 to 10; (2) 15 additional questions—in no particular order—that were also of high but lesser importance; and (3) up to 10 questions of lowest priority in laying the foundation for a CEA of nano-Ag. Participants also were invited to submit modifications of existing questions from the case study and new questions not included in the document. All revised and new questions were compiled and distributed to the workshop participants via email one week before the workshop, and the questions were included in the folders of materials provided to the participants at the workshop. During the initial plenary session at the workshop, the facilitators presented the results of the pre-workshop ranking of the questions. Figure 1-3 presents the pre-workshop ranking results for the top ten ranked questions. The instructions to participants detailing the pre-workshop ranking procedure are presented in Section 4.3 of this report; lists of new and revised questions are included in Section 4.4; and the pre-workshop ranking results for all questions and the methodology used to analyze the results are presented in Section 4.5.

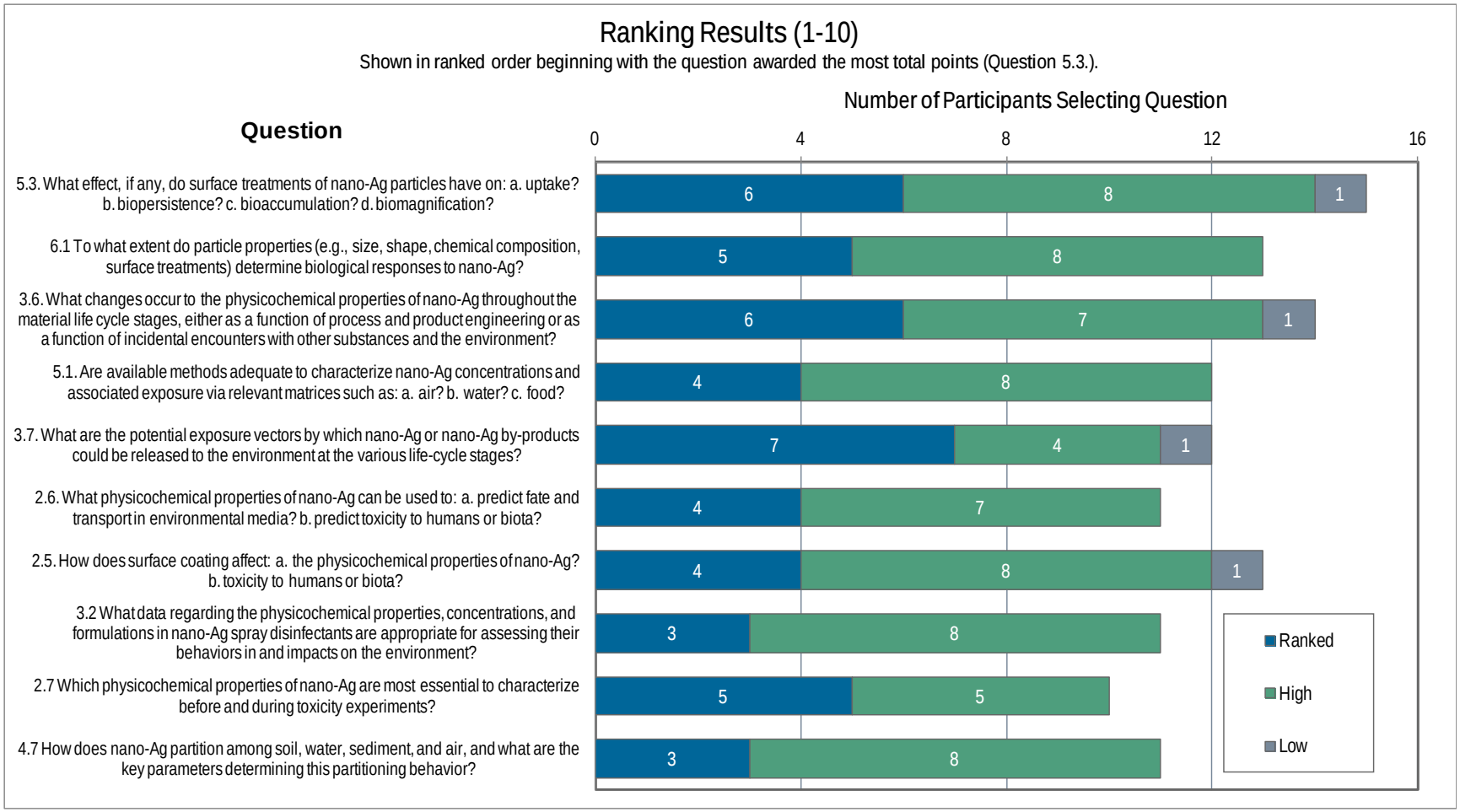


Figure 1-3. Pre-workshop ranking results for the top ten research questions posed in the nanosilver case study document.

1.4. Workshop Activities

This section describes several key workshop-related activities, including an EPA Public Information Exchange, the NGT process, and development of reports by participants.

1.4.1. Information Exchange and Introduction

Prior to and separate from the workshop, EPA convened a Public Information Exchange to explain the rationale for the case study approach, the choice of nanomaterials and applications, and the results from the 2009 workshop on nano-TiO_2. During the exchange, EPA clarified that ICF would conduct the Nanomaterial Case Study Workshop on Nano-Ag independently of EPA, with EPA funding, in compliance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix 2; see http://www.gsa.gov/portal/content/100916).

1.4.2. Nominal Group Technique

A description of the NGT process was provided to participants in advance of the workshop (see text box on the following page). The workshop agenda (Section 4.1) provides further detail about how the meeting was conducted.

The workshop was structured to introduce participants to NGT in the opening plenary session, when the pre-workshop ranking results also were presented and discussed to stimulate further thought about the relative importance of the various questions. At the end of the session, participants were asked to carefully consider and then select the top research priorities, along with rationales, for presentation during the NGT round robin.

The round-robin procedure allowed individuals up to 3 minutes each to present to the group a single high priority research/information need and a rationale for selecting that issue in relation to conducting a CEA. Participants also were allowed to present an entirely new question or to modify the phrasing or content of an existing research question. Each high priority research need was written on a flip-chart to enable consideration by the group. After each participant had spoken, the procedure was repeated for two more rounds, until all research priorities were posted on the wall. Altogether, participants identified 78 research issues as information needs during this stage: 58 unique issues and 20 issues that more than one participant proposed (see Section 2).

The second part of the NGT process involved consolidating similar or overlapping research needs into related research topic areas. Participants were given the opportunity to propose consolidating two or more research needs into a research theme, subject to approval by those participants who had nominated the respective research needs in question. Participants indicated that consolidation into research themes would be easier if the research questions were grouped by topic. Participants then divided those topics into research themes according to instruction by the facilitator that the themes should be amenable to being addressed in a single request for proposals or applications. The facilitator also reiterated the need to consolidate individual research needs into research themes to allow the participants to develop breakout group reports to ultimately guide future research prioritization.

The individual research questions were retained for later reference. Altogether, 56 of the 58 unique research needs were categorized into 23 consolidated research needs. Ten of the unique research needs were assigned to two consolidated research needs: 2.5, 2.6, 4.6, 4.10, 5.17, 6.8, 6.10, 6.16, N.9, and N.12.

Description of Nominal Group Technique

This summary was distributed to workshop participants and observers prior to the workshop.

Nominal Group Technique (NGT) is a structured process for a set of individuals to identify and rank a number of choices. Typically, several individuals (nominally a group) are convened and each person is afforded an equal opportunity to offer his or her view(s) about which choices are highest priority. When a large number of choices are under consideration, they may be grouped or consolidated into a more manageable number. A multi-voting process is then used to rank the choices. In the January 2011 Nanomaterial Case Studies Workshop, the participants will form one NGT group of approximately 25 individuals. This brief document provides an overview of NGT as it will be implemented at this workshop.

Round Robin Discussions. Each participant will be asked to state and provide justification for the research question they believe embodies the most important research or information need with respect to nano-Ag. This brief oral presentation (to be conducted without visual aids) must be completed within a **3-minute period** (strictly enforced). Each presentation should include a statement or description of the research question and an explanation of why it is a high priority in relation to a comprehensive environmental assessment of nanoscale silver (nano-Ag). As time permits, additional priorities will be presented in subsequent rounds of presentations. If another participant precedes you and speaks to the issue you intended to present, you may use your time in support of the same issue or you may raise a different issue that you consider to also be a high priority.

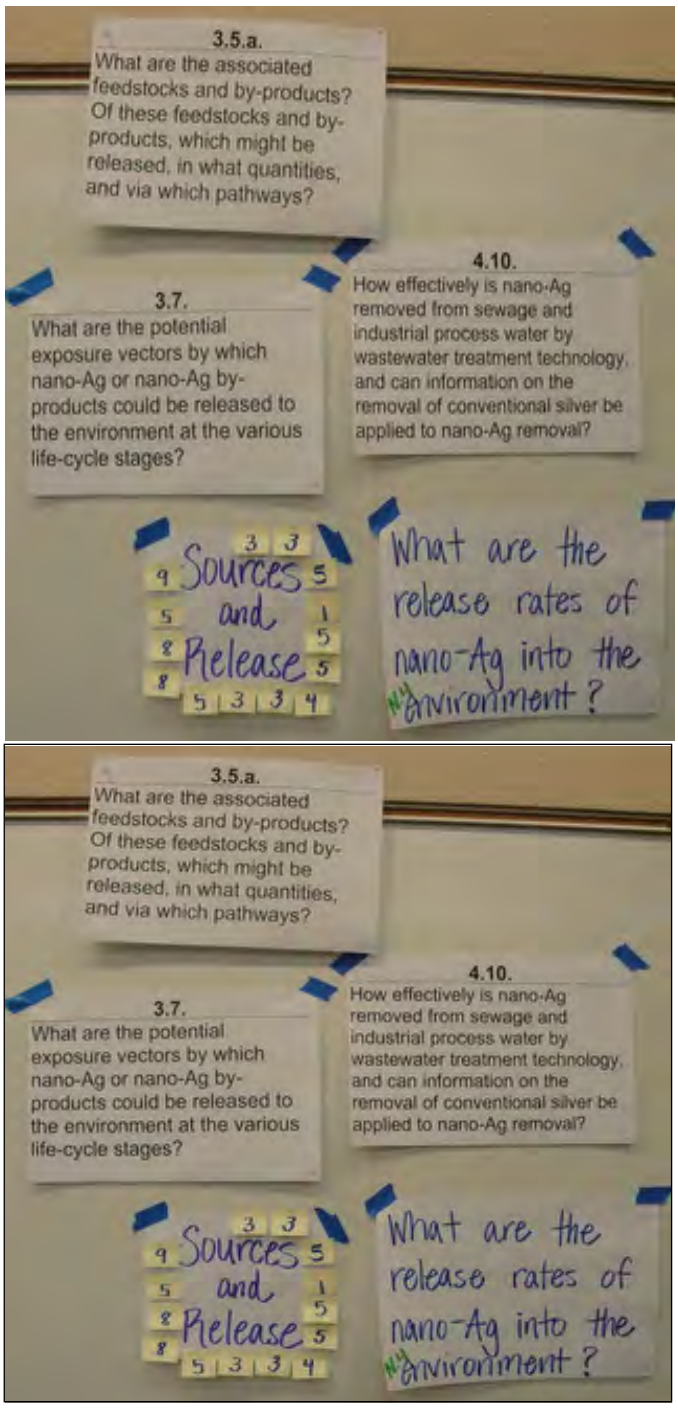
Consolidation and Multi-Voting. Each research question will be noted on a large sheet of paper and displayed for the group. A facilitator will work with the group to determine which questions can be consolidated into major research areas, thereby consolidating the total number of questions to around 20–30 themes. The consolidation process will be followed by multi-voting, during which participants will assign weighted votes to the research questions they deem most important for supporting a comprehensive environmental assessment of nano-Ag. The pre-workshop ranking process used multi-voting to develop a preliminary list of the top 10 questions, and essentially the same process will be used during the workshop.

Breakout Group Discussions and Summaries. After the group has prioritized the research questions through multi-voting, the participants will convene to discuss the ranking results. The participants will then be divided into breakout groups (each comprising 3 to 4 individuals), with each group assigned one of the top priorities. The breakout groups will discuss their assigned areas and prepare short written summaries in a standardized format that describe the research question of interest, explain what additional data are needed and why, and present other related information (including, as appropriate, alternate viewpoints). Then, the group will reconvene, review the next set of research questions based on the multi-voting results, and divide into new breakout groups to discuss the next set of priorities and develop another set of written summaries.

Plenary Discussion. Finally, the participants will reconvene in plenary and each of the summaries from the two sets of breakout groups will be presented. A primary objective of this final session will be to identify linkages among most highly ranked research areas.

The result of the workshop will be the set of the research questions selected through the NGT process as most important by the group. These questions and the summary information developed by the breakout groups will be incorporated into a workshop report.

The third part of the NGT involved a multi-voting exercise to develop a ranking of the consolidated research needs in terms of their importance for conducting a CEA. Each participant was given 10 Sticky Notes, labeled 1 to 10 with an identifying letter. The participants were then asked to rank their top 10 research priorities by giving 10 points to the research need they deemed most important for conducting the CEA, 9 points to their next highest priority, and so on, down to 1 point. Only 10 research topics could be ranked by an individual, and each topic could receive only one ranking per individual. After the voting process, the results were tallied and the ranked research priorities were identified. The ranking of research priorities is listed in Section 3.1.



Example of four questions consolidated into a research theme with multi-vote results.

1.4.3. Breakout Group Reports

The agenda was structured to allow for two separate breakout group sessions so that participants joined one breakout group in the morning and the other in the afternoon. At the 2009 workshop, only one breakout session was included for the most highly ranked themes (ranked 1 through 8). By scheduling two separate breakout group sessions for the 2011 workshop, participants could create reports for the most highly ranked themes (ranked 1 through 7) and also for the middle tier themes (ranked 8 through 14). This approach enabled participants equal opportunity to contribute to one highly ranked theme and one middle tier theme, rather than some participants contributing to two highly ranked themes and other participants contributing to two middle tier themes. It also expanded the number of consolidated themes on which participants created reports from 8 in the 2009 workshop to 13 (with one research topic omitted) in the 2011 workshop.

Participants volunteered to work on an issue of their choice (with guidance to limit group sizes to 3 or 4 people), resulting in 13 breakout groups corresponding to the top 14 research topics. Participants omitted one research topic (human and mammalian test methods) for a breakout group presentation, but the 13 remaining breakout groups were instructed to reference this topic in their reports. The groups were given around 3 hours for each breakout group session (including lunch) to develop a short report fleshing out descriptions of the research topic areas using an MS Word document template

(Section 4.6). The facilitator observed the breakout groups, offering guidance when appropriate. The written reports are presented in full in Section 3.2 of this report. On the last day of the workshop, a spokesperson from each breakout group gave a 5-minute presentation to the plenary group, using a provided PowerPoint template (Section 5). These presentations were meant to summarize each breakout group's written report, with particular emphasis on the topic's connections to other priority areas. Time was allowed for the plenary group to respond to these presentations, especially for the purpose of pointing out additional connections or relationships among research topic areas. The presentations and discussion points are also presented in Section 3.2 of this report.

ANNEXURE A6
37

Publications in the Series on the Safety of Manufactured Nanomaterials

The purpose of the OECD Series on the Safety of Manufactured Nanomaterials is to provide up-to-date information on the OECD activities related to human health and environmental safety.

WHAT'S NEW

Physico-chemical properties for nanomaterials can differ from those commonly considered for non-nanomaterials challenging their risk assessment. The OECD developed tools to identify which test methods are (or are not) appropriate to measure a given physico-chemical parameter considered key to characterization and identification, for a given type of nanomaterial. Together, the Physical-Chemical Decision Framework to inform Decisions for Risk Assessment of Manufactured Nanomaterials and its Guiding Principles are collectively intended to facilitate the identification of the most useful parameters and best available methods while maintaining rigour in data quality and reporting. Together they offer an approach to gather fit-for-purpose physico-chemical information to more fully understand the behaviour of nanomaterials in biotic and abiotic systems.

2021 REPORTS

- No. 348 - Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials; Part III: Performance testing results of tools/models for consumer exposure
- No. 347 - Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials; Part II: Performance testing results of tools/models for occupational exposure (Annex 1)
- No. 346 - Evaluation of Tools and Models for Assessing Occupational and Consumer Exposure to Manufactured Nanomaterials; Part I: Compilation of tools/models and analysis for further evaluation
- No. 345 - Evaluation of Tools and Models Used for Assessing Environmental Exposure to Manufactured Nanomaterials; Functional Assessment and Statistical Analysis of Nano-Specific Environmental Exposure Tools and Models

2020 REPORTS

- No. 97 - Developments in Delegations on the Safety of Manufactured Nanomaterials – Tour de Table
- No. 96 - Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products
- No. 95 - Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation/ PART3: Workshop Report and Recommendations
- No. 94 - Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation/ PART2: Case Study on Tissue Injury
- No. 93 - Advancing Adverse Outcome Pathway (AOP) Development for Nanomaterial Risk Assessment and Categorisation/ PART1: Final Project Report and Recommendations with Methodology to Prioritise Key Events (KEs) Relevant for Manufactured Nanomaterials
- No. 92 - Ability of biopersistent/biodurable manufactured nanomaterials (MNs) to induce lysosomal membrane permeabilization (LMP) as a prediction of their long-term toxic effects

2019 REPORTS

- No. 91 - Guiding Principles for Measurements and Reporting for Nanomaterials: Physical Chemical Parameters
- No. 90 - Physical-Chemical Decision Framework to inform Decisions for Risk Assessment of Manufactured Nanomaterials (see accompanying worksheets)
- No. 89 - Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table

2018 REPORTS

- No. 88 - Investigating the Different Types of Risk Assessments of Manufactured Nanomaterials
- No. 87 - Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table
- No. 86 - Assessment of Biodurability of Nanomaterials and the Surface Ligands
- No. 85 - Evaluation of in vitro methods for human hazard assessment applied in the OECD Testing Programme for the Safety of Manufactured Nanomaterials
- Test Guideline 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media **-** *Spreadsheet to be used in conjunction with TG 318* (Excel)
- Test Guideline 412: 28 days (Subacute) Inhalation Toxicity Study
- Test Guideline 413: 90 days (Subchronic) Inhalation Toxicity Study

2017 REPORTS

- No. 84 - Consumer and Environmental Exposure to Manufactured Nanomaterials -Information Used to Characterize Exposures: Analysis of a Survey
- No. 83 - Silver Nanoparticles: Summary of the Dossier
- No. 82 - Strategies, Techniques and Sampling Protocols for Determining the Concentrations of Manufactured Nanomaterials in Air at the Workplace
- No. 81 - Developments in Delegations on the safety of manufactured nanomaterials (March 2017 - August 2017)
- No. 80 - Alternative testing strategies in risk assessment of manufactured nanomaterials: current state of knowledge and research needs to advance their use

2016 REPORTS

- No. 79 - Strategy for Using Metal Impurities as Carbon Nanotube Tracers
- No. 78 - Developments on the Safety of Manufactured Nanomaterials Tour de Table from OECD Delegations (Nov. 2015- Oct 2016)
- No. 77 - Gold Nanoparticle Occupational Exposure Assessment in A Pilot Scale Facility
- No. 76/ADD - Grouping and Read-Across for the Hazard Assessment of Manufactured Nanomaterials: Participants List to the Expert Meeting
- No. 76 - Grouping and Read-Across for the Hazard Assessment of Manufactured Nanomaterials
- No. 75 - Future Challenges Related to the Safety of Manufactured Nanomaterials: Report from the Special Session
- No. 74 - Exposure Assessment of Nano-Silver (AgNP):Case Study
- No. 73 - Titanium Dioxide: Summary of the Dossier
- No. 72 - Toxicokinetics of Manufactured Nanomaterials: Report from the OECD Expert Meeting (2016)
- No. 71 - Silicon dioxide: summary of the dossier
- No. 70 - Single walled carbon nanotubes (SWCNTs): summary of the dossier
- No. 69 - Fullerenes (C60): summary of the dossier
- No. 68 - Multiwalled carbon nanotubes (MWCNT): summary of the dossier
- No. 67 - Developments in delegations on the safety of manufactured nanomaterials - Tour de table
- No. 66 - Categorisation of manufactured nanomaterials
- No. 65 - Physical-chemical properties of nanomaterials: Evaluation of methods applied in the OECD-WPMN testing programme
- No. 64 - Approaches on nano grouping/ equivalence/ read-across concepts based on physical-chemical properties (GERA-PC) for regulatory regimes
- No. 63 - Physical-chemical parameters: measurements and methods relevant for the regulation of nanomaterials

2015-2006 REPORTS

- No. 62 - Considerations for using dissolution as a function of surface chemistry to evaluate environmental behaviour of nanomaterials in risk assessments: Preliminary Case Study Using Silver Nanoparticles
- No. 61 - Developments in delegations on the safety of manufactured nanomaterials - Tour de table zzz
- No. 60 - Developments in delegations on the safety of manufactured nanomaterials - Tour de table
- No. 59 - Developments on the Safety of Manufactured Nanomaterials: 2013
- No. 58 - Preliminary guidance notes on Nanomaterials: Interspecies variability factors in human health risk assessment
- No. 57 - Guidance Manual towards the Integration of Risk Assessment into Life Cycle Assessment of Nano-Enabled Applications
- No. 56 - Analysis of the Survey on Available Methods and Models for Assessing Exposure to Manufactured Nanomaterials
- No. 55 - Harmonized Tiered Approach to Measure and Assess the Potential Exposure to Airborne Emissions of Engineered Nano-Objects and their Agglomerates and Aggregates at Workplaces
- Nos. 44-54 - Dossiers derived from the Testing Programme on Manufactured Nanomaterials available at: http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm
- No. 43 - Genotoxicity of Manufactured Nanomaterials : Report of the OECD expert meeting
- No. 42 - Report of the questionnaire on regulatory regimes for manufactured nanomaterials 2010-2011
- No. 41 - Report of the OECD expert meeting on the physical chemical properties of manufactured nanomaterials and test guidelines + Addendum
- No. 40 - Ecotoxicology and Environmental Fate of Manufactured Nanomaterials: Test Guidelines + Addendum
- No. 39 - Workshop on Environmentally Sustainable Use of Manufactured Nanomaterials, September 2011, Rome, Italy
- No. 38 - Co-Operation on Risk Assessment: Prioritisation of Important Issues on Risk Assessment of Manufactured Nanomaterials - Final Report
- No. 37 - Developments on the Safety of Manufactured Nanomaterials - Tour de Table - 10th Meeting of the Working Party on Manufactured Nanomaterials
- No. 36 - Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials
- No. 35 - Inhalation Toxicity Testing: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document
- No. 34 - Developments on the Safety of Manufactured Nanomaterials - Tour de Table - 9th Meeting of the Working Party on Manufactured Nanomaterials
- No. 33 - Important Issues on Risk Assessment of Manufactured Nanomaterials
- No. 32 - National Activities on Life Cycle Assessment of Nanomaterials
- No. 31 - Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information
- No. 30 - Regulated Nanomaterials: 2006-2009
- No. 29 - Developments/Activities on the Safety of Manufactured Nanomaterials - Tour de Table - 8th Meeting of the Working Party on Manufactured Nanomaterials - ENV/JM/MONO(2011)12
- No. 28 - Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories - ENV/JM/MONO(2010)47
- No. 27 - List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision
- No. 26 - Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table - 7th Meeting of the Working Party on Manufactured Nanomaterials
- No. 25 - Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision
- No. 24 - Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials
- No. 23 - Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (2010)
- No. 22 - OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012 Operational Plans of the Projects
- No. 21 - Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a regulatory context, September 2009, Washington D.C., USA
- No. 20 - Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table - 6th Meeting of the Working Party on Manufactured Nanomaterials, October 2009
- No. 19 - Analysis of Information Gathering Initiatives on Manufactured Nanomaterials
- No. 18 - Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010
- No. 17 - Developments in Delegations and other International Organisations on the Safety of Manufactured Nanomaterials - Tour de Table

- No. 16 - Manufactured Nanomaterials: Work Programme 2009- 2012
- No. 15 - Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials
- No. 14 - Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme (This document has been updated)
- No. 13 - Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials
- No. 12 - Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials
- No. 11 - Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance
- No. 10 - Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials
- No. 10 - Identification, compilation et analyse de documents d'orientation pour la mesure de l'exposition et la limitation de l'exposition : les nanomatériaux manufacturés
- No. 9 - EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs
- No. 8 - Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials
- No. 7 - Developments/Activities on the Safety of Manufactured Nanomaterials - Tour de Table - 4th Meeting of the Working Party on Manufactured Nanomaterials, June 2008
- No. 6 - List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme
- No. 5 - Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table - 3rd Meeting of the Working Party on Manufactured Nanomaterials, November 2007
- No. 4 - Manufactured Nanomaterials: Programme of Work 2006-2008
- No. 3 - Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de table - 2nd Meeting of the Working Party on Manufactured Nanomaterials, April 2007
- No. 2 - Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de table - 1st Meeting of the Working Party on Manufactured Nanomaterials, October 2006
- No. 1 - Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication, December 2005

FIND OUT MORE

- Testing Programme of Manufactured Nanomaterials

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 13, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 20, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

For the reasons stated in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart RR—Tennessee

■ 2. Section 52.2220(e) is amended by adding a new entry ''110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 NAAQS'' at the end of the table to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
*	*	*	*	* * *
110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 NAAQS.	Tennessee	03/13/2014	1/12/2017, [Insert citation of publication].	With the exception of sections: 110(a)(2)(C) and (J) concerning PSD permitting requirements and; 110(a)(2)(D)(i) (prongs 1 through 4) concerning interstate transport requirements.

[FR Doc. 2017–00161 Filed 1–11–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 704

[EPA–HQ–OPPT–2010–0572; FRL–9957–81]

RIN 2070–AJ54

Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is establishing reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale as described in this rule. Specifically, EPA is requiring persons that manufacture (defined by statute to include import) or process, or intend to manufacture or process these chemical substances to electronically report to EPA certain information, which includes insofar as known to or reasonably ascertainable by the person making the report, the specific chemical identity, production volume, methods of manufacture and processing, exposure

and release information, and existing information concerning environmental and health effects. This rule involves one-time reporting for existing discrete forms of certain nanoscale materials, and a standing one-time reporting requirement for new discrete forms of certain nanoscale materials before those new forms are manufactured or processed.

DATES: This final rule is effective May 12, 2017.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2010–0572, is available electronically at *http://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8974; email address: *alwood.jim@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Who does this action apply to?

You may be potentially affected by this action if you manufacture or process or intend to manufacture or process nanoscale forms (forms with particle sizes of 1–100 nm) of certain chemical substances as defined in section 3 of TSCA. You are not manufacturing or processing a TSCA chemical substance when you are manufacturing or processing a chemical for use as, *e.g.,* a pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act), food, food additive, drug, cosmetic or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act). However, persons that manufacture or process, or intend to manufacture or process these chemical substances as part of articles, as impurities, or in small quantities solely for research and development will not be subject to this action. In addition, the discussion in Unit III. describes in more detail which chemical substances will and will not be subject to reporting under the rule. You may also consult 40 CFR 704.3 and 704.5, as well as the regulatory text in this document, for further information on the applicability of these and other exemptions to this rule.

The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document may apply to them:

- Chemical Manufacturing or Processing (NAICS codes 325).
- Synthetic Dye and Pigment Manufacturing (NAICS code 325130).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- Rolled Steel Shape Manufacturing (NAICS code 331221).
- Semiconductor and Related Device Manufacturing (NAICS code 334413).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Home Furnishing Merchant Wholesalers (NAICS code 423220).
- Roofing, Sliding, and Insulation Material Merchant Wholesalers (NAICS code 423330).
- Metal Service Centers and Other Metal Merchant Wholesalers (NAICS code 423510).

B. What action is the Agency taking?

On April 6, 2015 (80 FR 18330; FRL–9920–90) (Ref. 1), EPA proposed reporting and recordkeeping requirements for persons that manufacture (including import) or process certain chemical substances as described in the proposed rule. EPA received numerous public comments and conducted a public meeting on June 11, 2015 to obtain additional public input. This final rule is based on that proposal and the consideration of the public comments received.

This TSCA section 8(a) rule requires one-time reporting of certain information, including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety information; as well as keeping records of this information for 3 years. EPA is finalizing the proposed requirements with changes to the definition of a reportable chemical substance, including a definition of unique and novel properties and a numerical value to replace the proposed term of trace amounts. There are also additional exemptions to reporting for certain biological materials, while zinc oxide and nanoclays are no longer exempt from reporting. The definition of a small manufacturer or processor exempt from reporting requirements has been changed. These changes, the reasons for the changes, and other clarifications are discussed in more detail in Unit III. EPA has also prepared a detailed response to public comments document (Ref. 2) that is available in the docket. EPA's responses to some of those comments are summarized in Unit III.

C. Why is the Agency taking this action?

These reporting and recordkeeping requirements will assist EPA in its continuing evaluation of chemical substances manufactured at the nanoscale, informed by available scientific, technical and economic evidence. As with current new chemical reviews of chemical substances manufactured at the nanoscale, each nanoscale material derived from substances on the TSCA inventory would be evaluated on a case-by-case basis without a presumption of either harm or safety. Any evaluation will be based on the specific nanoscale material's own properties and those of any structural analogs.

As indicated in the proposed rule, the requirements of the rule are not based on an assumption that nanoscale materials as a class, or specific uses of nanoscale materials, necessarily give rise to or are likely to cause harm to people or the environment. Rather, any information gathered under this rule will facilitate EPA's determination of whether further action, including additional information collection, is needed for that specific nanoscale material. Consistent with the President's memorandums for Executive Agencies regarding Principles for Regulation and Oversight of Emerging Technologies and U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials (Ref. 3), this rule will facilitate assessment of risks and risk management, examination of the benefits and costs of further measures, and making future decisions based on available scientific evidence.

In addition, EPA will not publish an inventory of chemical substances manufactured at the nanoscale based on the information that will be collected pursuant to the rule. EPA will make non-confidential information reported

under the rule available in ChemView (see *http://www.epa.gov/chemview/*).

D. What is the Agency's authority for taking this action?

As described in more detail in Unit II.A. of the proposed rule, the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA), 15 U.S.C. 2601 *et seq.,* provides EPA with authority to require reporting, recordkeeping and testing, and impose restrictions relating to chemical substances and/or mixtures. The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

EPA is issuing this rule under TSCA section 8(a), 15 U.S.C. 2607(a), in compliance with the requirements of section 8(a)(5). Under TSCA section 8(a)(5)(A) EPA is to the extent feasible: (A) Not require reporting which is unnecessary or duplicative; (B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and (C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of TSCA. As noted in the response to comments several elements of this rule address duplicative reporting such as the exemption for chemical substances that are nanoscale materials that have already been reported under section 5 of TSCA and for the exemption for information already submitted under the Nanoscale Materials Stewardship Program. The response also explains why this rule does not duplicate chemical data reporting (CDR) under 40 CFR part 711. EPA's economic analysis demonstrated that this rule would not have a significant adverse economic impact on a substantial number of small entities. The rationale supporting this conclusion is summarized in Unit V.C. of this rule and is presented in the small entity impact analysis that EPA prepared for this action as part of the Agency's economic analysis in the public docket for this rule. This rule focuses on manufacturers and processors of chemical substances as nanoscale materials with unique and novel properties which are the persons likely to have relevant information on nanoscale materials in commerce.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of this reporting and recordkeeping requirement for manufacturers and processors. This analysis (Ref. 4), which is available in the docket, is briefly summarized here.

Industry is conservatively estimated to incur a burden of approximately 360,000 hours in the first year and 40,100 hours in subsequent years, with costs of approximately $27.79 million and $3.09 million, respectively (see Chapter 3 in Ref. 4), while the Agency is expected to use approximately 16,300 hours in the first year and 1,800 hours in subsequent years, with costs of approximately $1.34 million and $0.15 million respectively (see Chapter 4 in Ref. 4). Discounted over a 10-year period at three and seven percent, total annualized social costs are estimated to be approximately $5.71 million and $6.26 million, respectively. (Ref. 4).

II. Overview of the Final Rule

EPA is describing in this unit the reporting and recordkeeping requirements for manufacturers and processors of certain chemical substances pursuant to TSCA section 8(a). A processor is someone who prepares a chemical substance or mixture after its manufacture for distribution in commerce. Processor activities include a variety of activities. Some examples of processing of a chemical substance are developing or modifying formulations for additional processing or use in commercial applications, incorporating a chemical substance into articles, and using the chemical substance to form other chemical substances.

A. What chemical substances are reportable under this rule?

1. Reportable chemical substances. This rule applies to chemical substances, as defined in section 3 of TSCA, that are solids at 25 °C and standard atmospheric pressure; that are manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nanometers (nm) in at least one dimension; and that are manufactured or processed to exhibit one or more unique and novel properties. This rule does not apply to chemical substances manufactured or processed in forms that contain less than 1% by weight of any particles, including aggregates and agglomerates, in the size range of 1–100 nm. These parameters are for purposes of identifying chemical substances that are subject to the rule and do not establish a definition of nanoscale material.

EPA added a definition of unique and novel properties in the definitions section of the regulatory text (See 704.20(a)). Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form or size. A reportable chemical substance is not just a substance containing particles in the size range of 1–100 nm; it must also demonstrate a size-dependent property different from properties at sizes greater than 100 nm and is a reason the chemical is manufactured or processed in that form or size. Chemical substances manufactured or processed at the nanoscale that contain incidental amounts of particles in the size range of 1–100 nm are not reportable chemical substances. EPA used ''trace amounts'' in the proposed rule to define this concept. However, based on the public comments to better define trace amounts including several comments to establish a numerical value, EPA is now using a numerical value of less than 1% of particles from 1–100 nm by weight to define those chemical substances that are not reportable.

i. Discrete forms. Manufacturers and processors of multiple nanoscale forms of the same chemical substance will, in some cases, need to report separately for each discrete form of the reportable chemical substance. Reporting of these discrete forms are not the same as new chemical reporting under TSCA section 5. The rule distinguishes between discrete forms in three different ways. The first is based on a combination of three factors: (1) A change in process to effect a change in size, a change in properties of the chemical substances manufactured at the nanoscale, or both; (2) a change in mean particle size greater than 7 times the standard deviation of the measured values (±7 times the standard deviation); and (3) the change in at least one of the following properties, zeta potential, specific surface area, dispersion stability, or surface reactivity, is greater than 7 times the standard deviation of the measured values (±7 times the standard deviation).

For example, if the specific surface area of one discrete form was measured to be 50 m^2/g with a standard deviation of ±5 m^2/g, then a change resulting in a new average specific surface area of 85 m^2/g would result in a discrete form of a reportable chemical substance, if factors 1 and 2 were also met. While testing is not required, if performing the test EPA recommends using the same test medium and method when measuring the change in these properties, as even minor changes in the

medium and methods can result in large differences in the measured results. EPA's intent for these reporting requirements is to focus reporting on chemical substances on the TSCA inventory that are intentionally manufactured at the nanoscale.

It is the combination of the above three factors, rather than simply size, which distinguishes between different forms of a chemical substance manufactured at the nanoscale, so that unintended variation in size range between production batches does not trigger separate reporting for each batch. The rule does not rely solely on process changes because there may be process changes that are not intended to change the material produced, but rather are intended to improve the efficiency of the process or to use a less expensive reactant. EPA is focusing on the properties of *zeta* potential, specific surface area, dispersion stability, and surface reactivity because these properties are of particular interest in health and safety evaluation. Other properties of chemical substances manufactured at the nanoscale (*e.g.,* the wavelength at which light is emitted) may be important for how that form of the chemical substance functions but are less likely to be relevant to hazard, fate, exposure, or risk. The combination of the above three factors provides a clear and transparent way to distinguish among discrete forms of chemical substances manufactured at the nanoscale for purposes of TSCA section 8(a) reporting.

For the purposes of this rule, specific surface area is the ratio of the surface area of the nanoscale material to its mass (m^2/kg), or the area of the surface of the nanoscale material divided by volume (m^2/m^3). This is an important factor because chemical reactions take place at the surface of the material. Thus, the higher the surface area, the greater the chemical reactivity, which is an important consideration for human health toxicity and environmental toxicity assessments.

Zeta potential is the electrostatic potential near the particle surface. It can be measured using various methods. See the International Organization for Standardization (ISO) ISO/TR 13014:2012 ''Guidance on Physicochemical Characterization for Manufactured Nano-objects Submitted for Toxicological Testing'' (Ref. 5) and the description of zeta potential by Colloidal Dynamics (Ref. 6) for examples. It is typically measured by electrophoresis. This is also an important factor as it measures chemical reactivity at the particle surface.

Dispersion stability is the ability of a dispersion to resist changes in properties over time and can be defined in terms of the change in one or more physical properties over a given time period. See ISO/TR 13097:2013 ''Guidelines for characterization of dispersion stability'' (Ref. 7) as an example. Changes in dispersion stability affect physical properties that in turn can affect the environmental fate and hazard properties of a chemical substance.

Surface reactivity is the degree to which the nanoscale material will react with biological systems. The surface reactivity of the form of a chemical substance is dependent upon factors such as redox potential, which is a measure of the tendency of a chemical species to lose or acquire electrons, and photocatalytic activity, including the potential to generate free radicals. Reactive oxygen species and free radicals are important in considering toxicity for these materials.

The second way of distinguishing a discrete nanoscale form of a particular chemical substance is by morphology or shape. Examples include spheres, rods, ellipsoids, cylinders, needles, wires, fibers, cages, hollow shells, trees, flowers, rings, tori, cones, and sheets. The third way is that forms of a reportable chemical substance that are coated with different chemical substances would be considered discrete forms for each chemical coating.

ii. Chemical mixtures. Chemical substances that are manufactured or processed in a nanoscale form for the purposes of being sold to others for use as a component of a mixture, encapsulated material, or composite are subject to reporting. Chemical substances at the nanoscale that are manufactured but are then incorporated into mixtures, encapsulated materials or composites by that manufacturer do not require separate reporting for their incorporation. However, the person reporting as to the chemical substance must report the information required as to each step of its manufacture, processing and use to the extent it is known or reasonably ascertainable.

2. Substances excluded from reporting. EPA is excluding from the requirements of this rule certain biological materials including DNA, RNA, proteins, enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms.

EPA is excluding chemical substances which dissociate completely in water to form ions with a size of less than 1 nm. This exclusion does not apply to chemical substances manufactured at the nanoscale that release ions but do not dissociate in water to form those ions. Chemical substances that dissociate completely in water to form ions with a size of less than 1 nm do not exhibit new size-dependent properties because the same properties would manifest in the dissociated form regardless of whether the substance is at the nanoscale before dissociation. Manufacturing or processing such substances are therefore not subject to the reporting requirements of the rule.

EPA is excluding chemical substances formed at the nanoscale as part of a film on a surface. See the explanation in Unit III. for the changes from the proposed rule and the detailed response to comments in the docket for EPA's explanation and reasoning.

3. General exemptions to TSCA Section 8(a) reporting. The general exemptions to TSCA section 8(a) reporting at 40 CFR 704.5 are applicable to this rule. These include, among other exemptions, the exemption for research and development (R&D) under which a person who manufactures or processes a chemical substance only in small quantities for research and development is exempt from the reporting requirements of this rule. Examples of R&D activity are the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance. It can include production of a chemical substance for use by others in their R&D activities. R&D activity generally includes specific monitored tests undertaken as part of a planned program of activity.

There is also an exemption from reporting for TSCA section 8(a) rules for small manufacturers and processors. For purposes of this rule EPA is defining and exempting any small manufacturer or processor as a company that has sales of less than $11 million per year.

4. Other exceptions to reporting. The rule does not require manufacturers or processors to report certain information that has already been submitted to EPA. A person who submitted a notice under TSCA section 5 to EPA for a reportable chemical substance on or after January 1, 2005 is not required to report regarding the same substance under this rule, except where the person manufactured or processed a new discrete form of the reportable chemical substance. In addition, any person who has already reported part of or all of the information that is required under this rule for EPA's Nanoscale Materials Stewardship Program (NMSP) would not need to report that information again under this rule. If, however,

information required by this rule was not reported under the NMSP (including information for each discrete form of a reportable chemical substance), then reporting of that information would be required under this rule. The purpose of these exemptions is to avoid duplicative reporting. For example, new chemical notices under TSCA section 5 that have been reviewed by EPA as nanoscale materials are not subject to reporting for the discrete form of a reportable chemical substance that was submitted and reviewed.

B. When will reporting be required?

Persons who manufacture or process a discrete form of a reportable chemical substance at any time during the three years prior to the final effective date of this rule must report to EPA one year after the final effective date of the rule. There is also a standing one-time reporting requirement for persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule. These persons must report to EPA at least 135 days before manufacture or processing of that discrete form except where the person has not formed an intent to manufacture or process a discrete form of a reportable chemical substance 135 days before such manufacturing or processing, in which case the information must be filed within 30 days of the formation of such an intent. For example, if a person forms the intent on July 1 to manufacture a reportable chemical substance and intends to commence manufacture of the substance in less than 135 days, that person must report the required information as to the chemical substance no more than 30 days after forming the intent, which would be July 31.

C. What information must be reported?

This rule requires one-time reporting of certain information, including specific chemical identity, actual or anticipated production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety information.

EPA developed a form (Ref. 8) for reporting information including specific chemical identity, material characterization, physical chemical properties, production volume, use, methods of manufacturing and processing, exposure and release information, and existing information concerning environmental and health effects. Any person required to report under this rule must supply the information identified in the form to the extent it is known to or reasonably ascertainable by them. EPA intends to issue guidance for the final rule within six months of issuing the rule including guidance on the reasonably ascertainable standard, consolidating submissions and generic chemical names.

D. How will information be submitted to EPA?

The rule requires electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA (see 704.20(e)). Submitters will use EPA's CDX, the Agency's electronic reporting portal, for all reporting under this rule. In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d). (Ref. 9) The final rule follows two previous rules requiring similar electronic reporting of information submitted to EPA for TSCA Chemical Data Reporting and for Pre-Manufacture Notices. EPA expects that electronic reporting will save time, improve data quality and increase efficiencies for both the submitters and the Agency.

EPA developed the Chemical Information Submission System (CISS) for use in submitting data for TSCA sections 4, 8(a), and 8(d) electronically to the Agency. The web reporting tool is available for use with Windows, iOS, Linux, and UNIX based computers, using ''Extensible Markup Language'' (XML) specifications for efficient data transmission across the Internet. CISS, a web-based reporting tool, provides user-friendly navigation, works with CDX to secure online communication, creates a completed document in Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML.

EPA is requiring submitters to follow the same submission procedures used for other TSCA submissions, *i.e.,* to register with EPA's CDX (if not already registered) and use CISS to prepare a data file for submission. Registration enables CDX to authenticate identity and verify authorization. To submit electronically to EPA via CDX, individuals must first register with that system at *http://cdx.epa.gov/epa_home.asp.* To register in CDX, the CDX registrant (also referred to as ''Electronic Signature Holder'' or ''Public/Private Key Holder'') agrees to the Terms and Conditions, provides information about the submitter and organization, selects a user name and password, and follows the procedures outlined in the guidance document for CDX available at *http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.*

Users who have previously registered with CDX for other TSCA submissions, Chemical Data Reporting, or the Toxics Release Inventory TRI–ME web reporting flow, can add the ''Submission for Chemical Safety and Pesticide Program (CSPP)'' CDX flow to their current registration, and use the CISS web-based reporting tool.

All submitters must use CISS to prepare their submissions. CISS guides users through the process of creating an electronic submission. Once a user completes the relevant data fields, attaches appropriate PDF files, or other file types, such as XML files, and completes metadata information, CISS validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Further instructions on submitting and instructions for uploading PDF attachments or other file types, such as XML, and completing metadata information are available through CISS reporting guidance.

CISS allows the user to choose ''Print,'' ''Save,'' or ''Transmit through CDX.'' When ''Transmit through CDX'' is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then encrypts the file and submits it via CDX. The user will log in to the application and check the status of their submissions. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as ''Completed.'' The CDX inbox is currently used to notify the users of any correspondence related to user registration. Information on accessing the CDX user inbox is provided in the guidance document for CDX at *http://www.epa.gov/cdr/tools/CDX_Registration_Guide_v0_02.pdf.* To access CISS go to *https://cdx.epa.gov/ssl/CSPP/PrimaryAuthorizedOfficial/Home.aspx* and follow the appropriate links and for further instructions to go *http://www.epa.gov/oppt/chemtest/ereporting/index.html.* Procedures for reporting chemical substances under this rule are similar.

Any person submitting a reporting form could claim any of the information on the form as CBI. Any information which is claimed as confidential will be disclosed by EPA only to the extent and by the means of the procedures set forth in 40 CFR part 2.

D. Confidentiality and the Recent Revisions to TSCA

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016, and became immediately effective. This final rule contains one minor change to reflect the new statutory requirements for asserting confidentiality claims. Section 14(c)(1)(B) of the law now requires a supporting statement for confidentiality claims. This statement is similar to the certification currently required in 40 CFR 704.7, which is cross-referenced in the proposed rule. In this final rule, EPA is substituting the wording of the section 14(c)(1)(B) statement for the wording of the certification in § 704.7(d) so as to eliminate any possibility of doubt that the certification meets the statutory requirements. While this change was not discussed in the proposed rule, EPA finds there is good cause to make this change without notice and comment. Notice and comment are unnecessary because the new statement is required by statute, and the new language is sufficiently similar to that in the § 704.7(d) certification that EPA anticipates no significant effect of the change on companies reporting under the rule or on the public in general.

The law also requires that a generic chemical identity be provided when companies claim a specific chemical identity as confidential. No conforming change is necessary for this rule, because companies reporting under this rule will be claiming chemical identities as confidential only when there is already a generic identity on the confidential portion of the TSCA Chemical Substances Inventory. CISS will automatically populate the submission with the generic chemical name associated with the Inventory listing. This process provides the greatest degree of structural specificity that is practicable to afford at the current time. EPA will develop guidance regarding generic names as required by TSCA, and will determine appropriate procedures regarding their use and submission.

III. Summary of Response to Comments Including Changes and Clarifications From the Proposed Rule

This unit summarizes EPA's responses to comments for several general areas of comments from multiple stakeholders, and where responses are particularly relevant to the requirements of the final rule. EPA also discusses any changes to and clarifications from the proposed rule. A separate document that summarizes the comments relevant to the proposal and EPA's responses to those comments has been prepared and is available in the docket for this rulemaking (Ref. 2).

Comment 1: Several commenters stated that TSCA applies to chemical substances, not different physical forms or different particle sizes of chemical substances, and that discrete forms or discrete physical forms are not ''chemical substances'' subject to reporting under section 8(a) of TSCA.

Response: TSCA section 8(a) authorizes EPA to promulgate rules for submission of such reports as the Agency ''may reasonably require.'' EPA believes that the information from this reporting will help EPA to determine whether chemical substances manufactured and processed at the nanoscale may exhibit behavior relevant to health and safety that is different from that of non-nanoscale forms of chemical substances. EPA thus has the authority to require reporting pertaining to different forms of chemical substances.

Comment 2: Several commenters stated that the proposed information requests are outside those allowed by section 8(a) of TSCA. Commenters specifically identified material characterization including particle size and morphology, methods of manufacture, weight percent of impurities, environmental release information, general population, consumer exposure, risk management practices, and engineering controls. One commenter wanted EPA to explain more clearly the basis of authority for requesting information that does not fall within the scope of the clear statutory authority of TSCA section 8(a).

Response: Section 8(a) gives EPA broad authority to collect information that the Administrator may reasonably require. Section 8(a)(1) authorizes EPA to require reporting of such information with respect to chemical substances as the Administrator may reasonably require. Although it contains limitations with respect to requirements to report with mixtures and to chemical substances manufactured in small quantities for experimentation, those limitations are not relevant to the requirements imposed by this rulemaking. Section 8(a)(2) is best interpreted as listing examples of the kinds of information EPA can require reporting on under section 8(a)(1), not as limiting EPA's authority. If Congress had intended to impose limitations on the kinds of information EPA can collect under section 8(a)(1), it would have added them to the limitations it included in section 8(a)(1). EPA has always interpreted section 8(a) in this fashion, see 58 FR 63134 (November 30, 1993)—an interpretation that is supported by the legislative history of section 8(a), H.R. Conf. Rep. 94–1679, at 80 (1976); S. Rep. No. 94–698, at 22 (1976), H.R. Rep. No. 94–1341, at 42 (1976). Further, the information required under the rule is consistent with the examples of information discussed in section 8(a)(2). For example, requiring weight percent of impurities is analogous to byproducts, material characterization including particle size and morphology is analogous to molecular structure of chemical substances manufactured and processed at the nanoscale, environmental release falls under methods of disposal, while methods of manufacture, risk management practices, engineering controls, general population and consumer exposure fall under estimates of individuals who would be exposed.

Comment 3: Several commenters noted that processors do not know about the particle size and other characteristics of formulations they process or use and should not be required to report.

Response: Reporting of information under TSCA section 8(a) is required only to the extent the information is known or reasonably ascertainable, and includes information that the Administrator may reasonably require. This standard applies both to the extent of an entity's obligation to determine whether it is required to report, and to the extent of information any entity is required to report. If processors do not know about specific physical properties of chemical substances, they must still take reasonable measures to ascertain the information that would determine whether they are subject to the rule. If processors do not know about specific properties such as particle size and other properties that would allow them to know if they are processing a chemical substance subject to the rule, it would be within the reasonably ascertainable standard to ask their suppliers for information that would enable the processor to determine whether the supplier is selling them a nanoscale material subject to reporting and if so provide them with what reportable information they have. Their supplier is not required to provide any additional information to the processor but might provide other supporting information, for example, whether their supplier has reported or intends to report the chemical substance under this rule. If the supplier provides information indicating that the substance is not reportable or if the processor lacks any other means of

reasonably ascertaining whether the substance is reportable, the processor does not need to perform tests to determine whether the substance is reportable. Information developed in the normal course of business or that the processor chooses to develop must also be used. The processor may want to document the steps they took to determine if reporting was required. Companies that purchase formulations but do not change or modify those formulations and only use them are not considered processors and are not required to report.

If the information provided by the supplier indicates that reporting is required, the processor is required to report information that is known or reasonably ascertainable, which may include information obtained from the supplier. This would include situations where the processor may not know the exact chemical identity or some of its physical properties.

The obligations imposed by the reasonably ascertainable standard are discussed more fully in the Chemical Data Reporting final rule, 76 FR 50816, 50829 (August 16, 2011).

Comment 4: Several commenters also asked EPA if manufacturers and processors are only required to report available or reasonably ascertainable information, does this mean they need to develop information to comply with the rule. Other commenters asked EPA to clarify if manufacturers and processors need to develop information to comply with the rule.

Response: Manufacturers and processors are not required to conduct testing or develop new information under this rule. However, they are required to report information that is known or reasonably ascertainable.

Comment 5: Many commenters stated the proposal gives too much discretion to interpret compliance obligations. Commenters suggested clarifying the definition of unique and novel properties, adopting an alternative, or not using it at all. One commenter noted that if the requirement that reportable chemicals exhibit unique and novel attributes due to particle size is removed from the definition, the rule would not differentiate genuinely new nanoscale materials from traditional legacy products in commerce. Several commenters stated there should be some differentiation between genuinely new nanoscale materials in commerce and traditional products. Two commenters supported the proposed definition while one commenter supported a definition of 1–100 nm and unique or novel characteristics.

Response: Based on these comments, EPA agrees that what is a reportable chemical substance should be better defined and clarified. EPA is finalizing the rule with further explanation of ''unique and novel properties'' as described in the National Nanotechnology Initiative's definition. Some nanostructured materials are stronger or have different magnetic properties compared to other forms or sizes of the same material. Others are better at conducting heat or electricity. See *http://www.nano.gov.* They may become more chemically reactive or reflect light better or change color as their size or structure is altered. A property is novel when it is different from the properties associated with other forms or sizes of the same chemical substance. As also noted on *http://www.nano.gov,* when particle sizes of solid matter in the visible scale are compared to what can be seen in a regular optical microscope, there is little difference in the properties of the particles. But when particles are created with dimensions of about 1–100 nm, the materials' properties can change significantly from those at larger scales. See also comment 11 and the response for further clarification on what is considered a reportable chemical substance.

For purposes of this rule, EPA is defining unique and novel properties to include an element of intent, meaning that those properties are the reason why the chemical substance is manufactured in that form or size. The rule includes a definition of unique and novel properties in the definitions section of the regulatory text (See § 704.20(a)). Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form or size. In order to be reportable it's not sufficient that a chemical substance contains particles in the size range of 1–100 nm; it must also have a size-dependent property different from properties at sizes greater than 100 nm and those properties are a reason that the chemical substance is manufactured or processed in that form or size. Intentionally manufacturing or processing nanoscale gold so that it exhibits a red or purple color instead of a yellow color would create a unique or novel optical property seen at the nanoscale. Such a change would likely result in changes of other properties, such as specific surface area which can result in different health and safety impacts. Unique and novel properties which impact performance generally cannot be isolated from concurrent changes in properties that impact biological systems. For example, see the discussion in Unit II.B. of the proposed rule of the range of biological impacts of nanoscale materials. EPA is exempting certain biological materials, in part, because they do not exhibit different size-dependent properties in the size range of 1–100 nm.

Other chemical substances, including as an example some chemicals that commenters proposed that EPA exempt from reporting, such as pigments, polymers, and polymer dispersions, could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. In the concept paper for the NMSP (Ref. 10), EPA stated that many polymers or oligomers, particularly linear or planar polymers, should not be reported even though they have dimensions in the nanoscale. Those polymers did not demonstrate size-dependent properties. The paper did note that when conditions of polymerization or post-reaction processing create free particles that fit the general description of ''engineered nanoscale material'' those chemical substances should be reported under the NMSP. Please also refer to the comment and response to comment 12 in the response to comments document regarding the difference between enhanced and novel properties.

Comment 6: Several commenters suggested alternative definitions of trace amounts stating that the term in the proposed rule is not definitive and gives too much discretion to interpret compliance obligations. The commenters suggested including a numerical value to define trace amount. Most commenters did not suggest a specific value, although one commenter noted the original definition of the Agency's draft proposed rule submitted to OMB would have required reporting for those substances containing ≥10% particles in the range of 1–100 nm while another commenter suggested using a numerical value of less than 10% of particles as trace amount that would not be considered to be a reportable chemical substance. Commenters asked EPA to clarify if particle size was to be determined by weight, volume, or count. One commenter stated that EPA should not use weight based criteria to determine particle size as that measurement is sometimes skewed by the inclusion of very large particles. Several other commenters suggested using weight based criteria to identify particle size but did not give any reasons why.

Response: Chemical substances manufactured or processed at the nanoscale that contain incidental amounts of particles in the size range of 1–100 nm are not reportable chemical substances. EPA used trace amounts in the proposed rule to define this concept. However, based on the public comments to more clearly define trace amounts including several comments to establish a numerical cutoff, EPA is instead using a numerical value of less than 1% of particles from 1–100 nm by weight to more clearly define those chemical substances that would not be reportable. EPA has chosen this number because it is the percentage cut-off used in OSHA's hazard communication standard for all chemicals substances that are not OSHA carcinogens (for which there is a 0.1% cut-off) (Ref. 11). This 1% cut-off is a level that industry has used to identify chemicals in safety data sheets (and previously in material safety data sheets.) Industry is already using this cut-off to identify at least some nanoscale chemical substances, *e.g.,* carbon nanotubes in mixtures. EPA is using the weight based method for measuring particles even though that measurement is sometimes altered by the presence of very large particles because it is the most widely used method, and more data will therefore be available. The final rule does not require reporting for any chemical substance where less than 1% percent of the particle size distribution by weight is less than 100 nm.

Changes to the Definition of a Reportable Chemical Substance in the Final Rule. EPA has added a definition of unique and novel properties in the definitions section of the regulatory text (See 704.20(a)). Unique and novel properties means any size-dependent property that vary from other properties associated with other forms or sizes of the same chemical substance, and such properties are the reason that the chemical substance is manufactured or processed in that form or size. A reportable chemical substance is not just a substance containing particles in the size range of 1–100 nm; it must also have a size-dependent property different from properties at sizes greater than 100 nm. The final rule no longer states that a reportable chemical substance does not include a chemical substance that only has trace amounts of primary particles, aggregates, or agglomerates in the size range of 1–100 nm, such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size. The final rule now states that a reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates and agglomerates, measured by weight are in the size range of 1–100 nm.

Comment 7: A variety of commenters stated that EPA should add additional exemptions for biological materials such as enzymes, lipids, carbohydrates, peptides, polypeptides, nucleotides, liposomes, antibodies, viruses, virus-like particles, viral based products, organelles, and microorganisms. The commenters stated that the additional biological materials should be exempted for the same reason EPA proposed to exempt DNA, RNA, and proteins, that the additional biological materials did not exhibit properties as a function of their size range.

Response: Because they meet the same criteria that EPA identified in the proposed rule, EPA is adding an exemption for enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, and microorganisms in the final rule. The properties of all the exempted biological materials, which can be in the nanoscale, are not a function of the size range per se but rather of the precise nucleotide sequence (in the case of DNA and RNA), shape, and complex biological structures (living cells).

Comment 8: Several commenters identified additional possible exemptions for organic and inorganic pigments and dyes; polymers including polymer dispersions; and chemical substances used in adhesives, coatings and sealants and chemical substances when they are embedded in a polymer matrix or incorporated into a formulated product such as adhesives, cement, ink, coatings, glass, paint, plastic and rubber because they are well understood or characterized and present low risk and low potential for exposure. Commenters suggested that EPA include an exemption for polymers and polymer dispersions to be consistent with the polymer exemption under section 5 of TSCA. Commenters also noted TSCA section 5 regulations such as SNURs which exempted requirements for carbon nanotubes, silica, and pigments when incorporated into polymer matrices.

Response: A reportable chemical substance is not just a substance containing particles in the size range of 1–100 nm; it must also have a size-dependent property different from properties at sizes greater than 100 nm. The chemical substances or activities identified by commenters could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. If a chemical substance does not exhibit unique and novel properties, then no reporting would be required. EPA lacks information demonstrating minimal risk and exposure for nanoscale forms of the chemical substances or activities that commenters proposed for exemption. The polymer exemption under TSCA section 5 is not based on any consideration of the potential for impacts from polymers with size dependent properties and does not include all polymers. Most of the activities described by commenters for exemption would only require reporting for a reportable chemical substance before it is incorporated into a formulated product or polymer matrix. Reporting would not be required by persons who use the formulated product or polymer matrix. EPA is not including an exemption for these chemical substances and activities because doing so would exempt some of the nanoscale materials in commerce for which EPA is collecting information on health and safety effects which would allow EPA to better assess and manage risks of nanoscale materials.

Comment 9: Several commenters proposed limited or no reporting for nanoscale materials such as carbon black, silica, titanium dioxide, nanosilver, and nanocellulose, based on the proposed exemption for nanoclays and zinc oxide. The commenters asked EPA to better define the criteria it used to exempt nanoclays and zinc oxide as well-characterized so that the criteria could be applied to these chemical substances. One commenter noted that available information for commercial forms of nanocellulose demonstrate low hazard and risk. Several commenters also described the hazards and exposures of these chemical substances as well-characterized. Several commenters stated that EPA should not exempt zinc oxide and nanoclays as EPA had not identified and made available the data that demonstrated why they are well-characterized.

Response: EPA has decided to not exempt nanoclays and zinc oxide from reporting. When considering the comments to exempt other chemical substances based on its proposed exemption for zinc oxide and nanoclays, EPA realized that it had given too much weight to the available information on zinc oxide and nanoclays. While there is some available information on these chemical substances, EPA does not consider the available information sufficient to extrapolate to all other forms of these chemical substances to exclude information collection under TSCA. Further, this limited information

is not a sufficient basis to create a broader exemption by analogy for other chemical substances. Thus, even for chemical substances manufactured as nanoscale materials that could be described as a group as well-characterized or demonstrating low hazard based on data not relating to nanoscale forms in particular, EPA lacks information on how much and what type of specific nanoscale materials are in commerce and what kind of information is available to assess the properties that can impact health and safety and thus potential risks of those nanoscale materials. The chemical substances that commenters and EPA stated were well characterized could be manufactured in nanoscale forms that both exhibit unique and novel properties and in forms that do not. EPA is not exempting from reporting any of the chemical substances proposed by commenters, including zinc oxide and nanoclays because doing so would exempt some of the nanoscale materials in commerce for which EPA is collecting information on health and safety effects which would allow EPA to better assess and manage risks of nanoscale materials. The type of information described by the commenter regarding nanocellulose is the type of information on health and safety effects which would allow EPA to better assess and manage risks of nanoscale materials.

Changes to Chemical Substances That are Exempt from the Final Rule: EPA added exemptions for enzymes, lipids, carbohydrates, peptides, liposomes, antibodies, viruses, microorganisms in the final rule. EPA did not add any other exemptions to the final rule. EPA did not include the proposed exemptions for nanoclays and zinc oxide in the final rule.

Comment 10: Several commenters stated that EPA cannot require information that violates the language under TSCA section 8(a) prohibiting ''*any reporting which is unnecessary or duplicative.*'' *Commenters stated that requiring reporting of some of the information already reported to the NMSP would be duplicative, especially the large amount of health and safety information submitted for broad classes of chemical substances such as silica and carbon black. Commenters also asked EPA to explain why the proposed reporting requirements do not duplicate reporting required under CDR.*

Response: The reporting required by this rule does not duplicate reporting EPA would receive under other TSCA regulations. Chemical data reporting (CDR) under 40 CFR part 711 does not require manufacturers to distinguish reporting for different forms of chemical substances including nanoscale materials. This rule also exempts reporting for chemical substances that are nanoscale materials that have already been reported under section 5 of TSCA since 2005 except for new discrete forms. As noted in the interim report on the NMSP (Ref. 12), EPA received limited reporting on nanoscale materials in commerce. The reporting for nanoscale materials such as silica and carbon black gave an overview of the entire industry but not information on individual nanoscale materials. A company reporting a silica or carbon black-based nanoscale material does not have to resubmit the information submitted under the NMSP. However, any reporting of silica or carbon black nanoscale materials would need to include any health and safety information that company possesses for the specific nanoscale material it is reporting. As already noted, CDR reporting does not distinguish between different nanoscale forms of chemical substances. Several commenters stated that EPA needs more information on nanoscale materials in commerce. In the full response to comments document, EPA addresses more specific comments about information required by the rule.

Comment 11: There were numerous comments to not include the 135 day reporting requirement for new discrete forms. This requirement was characterized by several commenters as de facto new chemical reporting. Commenters also asked EPA to clarify if persons subject to the rule had to wait until the 135 day period was completed before commencing manufacture or processing. The 135 day reporting requirement was supported by several commenters because it provides the Agency with more time to identify potential concerns and initiate appropriate action to address them.

Response: EPA did not intend to create de facto new chemical reporting for new discrete forms of nanoscale materials, because the 135-day period is not a formal review-period that prohibits manufacture before the end of the 135-day period. Rather, based on EPA's experience with the Premanufacture Notice (PMN) program, EPA believes that in most cases companies have the requisite intent to manufacture or process at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent. However, if a company does not form the requisite intent 135 days ahead of time, the company must report within 30 days of the formation of such an intent. Moreover, if a company desires to begin manufacture or processing less than 135 days after the submission for this rule is made, the company is free to do so. There is no obligation upon the company to wait 135 days after reporting to manufacture or process. EPA is revising the language in 704.20(f)(2) to clarify that the rule does not prevent manufacturing before the 135-day period has passed. If the company changes its schedule or does not form the intent until a later time, it may wish to document supporting facts.

Further, the comments made EPA realize that the regulatory text as written in the proposal created a result unintended by the Agency (and not commented upon): Because (1) the default period of 135 days is greater than the advance of periods required for various section 5 submissions, and (2) the reporting exemption for section 5 submissions in 704.20(c)(2) of the proposal would apply only where the company *had already filed a section 5 submission,* a company proposing to manufacture a discrete form of a reportable substance for which a section 5 submission had not been filed might conceivably be required to first file a section 8(a) report, followed by a section 5 submission. In such cases EPA only needs the section 5 submission and exercise whatever section 5 authority might be necessary in a specific case, rather than imposing an additional burden of requiring a duplicative section 8(a) submission. Therefore EPA is adding a new subcategory of non-reportable chemical substances to 704.20(c)(1), for chemical substances that are not on the TSCA Inventory at the time reporting would otherwise be required, to clarify the Agency's original intent in the NPRM. If a reportable chemical substance is not on the TSCA Inventory a manufacturer only needs to submit a new chemical notification under section 5 of TSCA.

Changes to the 135-day Reporting Requirement for Discrete Forms of a Reportable Chemical Substance: EPA has added language to 40 CFR part 704.20(f)(2): ''except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.'' The language makes clear what companies must do if they do form an intent to manufacture or process a discrete form of a reportable chemical substance less than 135 days ahead of manufacture or processing.

Changes to Chemical Substances That Are Not Reportable: EPA has added language to 704.20(c)(1), exempting

chemical substances that are not on the TSCA Inventory from reporting.

Comment 12: There is not standardized testing for the physical properties in the proposed rule identified for manufacturers and processors to determine if they qualify for the rule. EPA should identify test methods to be used to comply with the rule. Many processors will not know to test for these properties. EPA cannot require this testing until validated protocols are developed.

Response: Testing or developing new information is not required by the rule. Only known or reasonably ascertainable information needs to be reported. Companies are only required to report on known or reasonably ascertainable information. See the response to comment 3 for guidance as to situations in which a company does not know about the physical properties identified in the regulation. In the proposed rule, EPA supplied examples of testing guidelines that could be used for these types of properties should the company desire to do such testing.

Comment 13: Several commenters supported the $4 million dollar small business exemption. One commenter wanted an even smaller dollar amount so that more small businesses would be required to report. Other commenters supported just using the dollar amount but stated it should be increased to $9.5 million dollars to account for inflation since 1988 when the current small business amount of $4 million was established.

Response: Based on these comments and updated economic information, EPA is changing the definition of small business in the final rule to include any company with sales of $11 million dollars or less. In suggesting EPA change the value to $9.5 million, the commenter assumed the original $4 million was promulgated in 1988. However, the $4 million was initially promulgated in 1984 (49 FR 45425) with a base year of 1983. Therefore, it is appropriate to inflate the $4 million from $1983 to $2015. When accounting for inflation since 1983, EPA calculated the figure to be $11 million dollars.

In proposing this definition, EPA provided notice and comment on the criteria for small manufacturers and processors subject to this rule, and consulted with the Small Business Administration (SBA) in accordance with TSCA section 8(a)(3)(B). EPA's change to this definition is consistent with both public comments and the feedback we received from SBA.

EPA recognizes that recent amendments to TSCA include a new and separate obligation under amended TSCA section 8(a)(3)(C), which requires EPA, after consultation with the SBA, to review the adequacy of the standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of TSCA sections 8(a)(1) and 8(a)(3). TSCA furthermore requires that (after consulting with the SBA and providing public notice and an opportunity for comment) EPA make a determination as to whether revision of the standards is warranted. In the **Federal Register** of December 15, 2016 (81 FR 90840) (FRL–9956–03), EPA sought public comment on whether a revision of the current size standard definitions is warranted at this time; announced EPA's initiation of the required consultation with the SBA, and provided its preliminary determination that revision to the currently codified size standards for TSCA section 8(a) is indeed warranted. As part of this effort, EPA will review the adequacy of the standards for small manufacturers and processors in existing TSCA section 8(a) rules, including this one. Any changes resulting from the assessment will undergo consultation with SBA and will be proposed for notice and comment as required by TSCA section 8(a)(3)(C).

Changes to the Definition of a Small Manufacturer or Processor Exempt from the Reporting Requirements of the Rule: The final rule retains a small business exemption based only on sales, but a small manufacturer or processor will be defined as any company with sales of less than $11 million per year.

Comment 14: Several commenters asked EPA to clarify the objects and collections of objects to which the 1–100 nm measurement applies. In other words, does that mean any form with particles 1–100 nm or does that include aggregates and agglomerates greater than 100 nm but based on primary particles less than 100 nm?

Response: Chemical substances required to be reported would include any form with particles 1–100 nm but would not include aggregates or agglomerates greater than 100 nm even if they contain primary particles less than 100 nm. EPA has modified the description of particles that would be subject to reporting in the definition of reportable chemical substance to better reflect this understanding. The language in the reportable chemical substance definition now reads, ''where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm''

Comment 15: Several commenters suggested that EPA should better define particle. One commenter stated ''The word 'particle' is not a term with specific meaning. It is critical that EPA is clear about the definition of 'particle' so that companies understand what materials require reporting. For example, does the term 'particle' include solid objects that contain internal crystalline domains at the nanoscale? Does it include dispersions, suspensions, or aerosols? A definition of 'particle' would provide an important starting point for determining whether a material is subject to reporting. It should take into account the ability of a 'particle' to move freely in its environment.''

Response: EPA will use the definition of particle from ISO, which is a ''minute piece of matter with defined physical boundaries.'' The notes to the ISO definition should be used as guidance in applying this definition. **Note 1:** A physical boundary can also be described as an interface. **Note 2:** A particle can move as a unit. EPA is using this definition because there is international agreement on the definition; the definition addresses the commenter's questions about the ability of a particle to move in the environment and whether ''particle'' includes dispersions, suspensions, or aerosols.

Changes to the Final Rule to Clarify the Types of Particles to be Measured: EPA has added a definition of particle and modified the language in the definition of reportable chemical substance for the types of particles that will be measured.

Comment 16: Several commenters stated that the shape criteria for identifying reportable chemical substances are too vague and unworkable. The commenters asked what the criteria are to discern one shape from another. For example one commenter stated ''For morphology, how would manufacturers and processors distinguish between the different morphologies identified in the proposed regulatory text: What definitions would distinguish for example a rod from an ellipsoid, needle, wire, and/or fiber as these shapes could be considered on a continuum? Another commenter stated ''It is unclear how different the shapes of two forms would have to be in order to trigger the discrete forms requirement.''

Response: As noted in the proposed rule the different morphology could be any change in the shape of particles. Different morphology does not include random shape changes or natural variation in shapes of particles that are not definitive and that, as commenters have noted, occur in a continuum. Some nanoscale materials are engineered to give all the particles a certain morphology or shape. The change in

shape needs to be a specifically engineered change in the shape of particles of a nanoscale material, to effect a change and form a unique and novel property for a chemical substance in the particle size range of 1–100 nm.

Comment 17: Several commenters objected to imposing the same reporting requirements on both processors and manufacturers stating that some processors will not be aware of information known to manufacturers such as for example chemical identity, physical-chemical properties, byproducts, impurities, health effects data, and general population exposure. In addition, the commenters speculated that processors may report uses and processes already reported by the manufacturer. The commenters felt the reporting requirements place impractical or burdensome obligations on processors without collecting information that would serve the intended purposes of the rule when manufacturers were in the best position to report information required by the rule. Commenters suggested limiting reporting to only manufacturers or limiting the information to be reported by processors.

Response: Processors are only required to submit information that is known or reasonably ascertainable. In addition, processors may have access to pertinent information that manufacturers do not have access to. Processors can often describe in greater detail how the nanoscale material is processed and used and any characteristics that change because of processing. Details on the processing and use of nanoscale forms of chemical substances with unique or novel properties will give EPA a better understanding regarding how to assess those chemical substances and whether any further actions are warranted under TSCA.

Comment 18: Several commenters stated that EPA should exempt naturally occurring or mined nanoscale materials. One commenter noted that CDR regulations exempt naturally occurring chemical substances as described at 40 CFR 710.4(b). Several commenters also stated naturally occurring nanoscale materials should be exempt from reporting as they do not meet the criteria of the definition of ''manufactured or processed.'' Another commenter suggested limiting reporting to engineered nanomaterials as they are ''generated for a specific function'' or ''deliberately manipulated.''

Response: EPA did not exempt naturally occurring materials or limit reporting to chemical substances engineered at the nanoscale because some of these chemical substances meet the criteria of a reportable chemical substance and some of them do not. These chemical substances must be reported only if they meet the definition of containing particles in the size range of 1–100 nanometers and a size-dependent property different from properties at sizes greater than 100 nanometers. EPA expects that reportable chemical substances would usually be the result of processing of naturally occurring or mined materials by manufacturers and processors

Comment 19: A commenter stated that EPA should add an explicit exemption for nanoscale substances that are unintentionally generated during manufacturing and processing. Another commenter asked EPA to clarify if it matters if a nanoscale substance is intentionally added versus accidentally formed.

Response: If a nanoscale chemical substance is unintentionally generated or added and not intended to be part of the commercially manufactured or processed chemical substance, it may be considered a byproduct or impurity and would be exempt under 40 CFR 704.5(b) or (c). If a nanoscale chemical substance is unintentionally formed but is considered to be part of the function of the commercial product, it would be a reportable chemical substance. A chemical substance which is intentionally produced but is in total or in part unintentionally produced at the nanoscale is not an impurity or a byproduct. There are examples where a chemical substance is intentionally produced, but unintentionally produced at the nanoscale, and the manufacturer knows that it contributes to the function of their product. In those cases, where a company knows about its functionality, the chemical substance is still subject to TSCA reporting requirements. See, for example, EPA's PMN regulations at 40 CFR 720.30(h)(2), which exempts from reporting a byproduct not used for commercial purposes, but retains the reporting requirement if the byproduct is used for commercial purposes. The rule does not require a company to determine the functionality of every impurity or byproduct. A company is required to report that chemical substance when it knows the chemical substance has commercial functionality.

Other Changes to the Final Rule: EPA made other changes to the rule. See the Response to Comments Document (Ref. 2) for further details. EPA has modified the definition of zeta potential to address public comments that zeta potential was not accurately defined in the proposed rule. Because ''chemical substances manufactured at the nanoscale as part of a film on a surface'' did not adequately describe the films on a surface exemption that was proposed, EPA changed the wording of the exemption to state ''chemical substances formed at the nanoscale as part of a film on a surface.''

Changes to the Reporting Form: EPA made the following changes to the reporting form. See the Response to Comments Document (Ref. 2) for further explanation. EPA removed the requirement for an overview of the life cycle in Section C of the reporting form, as that information duplicates information already identified in other parts of the form. Because not all enhanced properties are unique or novel properties, EPA replaced the word enhanced with novel in section C.5. of the reporting form. EPA added language to the form instructions that ''You may want to consult with your customers or suppliers about the confidentiality of any information you report about them on this form'' in response to comments that manufacturers or processors may not accurately identify confidential information obtained from suppliers or customers. In order to help facilitate continued work on sharing available information and to inform future alignment on activities pertaining to nanoscale materials, EPA included the option on the reporting form to share information with Environment and Climate Change Canada and Health Canada per one commenter's request to provide the option of sharing CBI.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; Proposed Rule. **Federal Register** April 6, 2015 (80 FR 18330) (FRL–9920–90).

2. 2016. EPA. Response to Comments to the Proposed Rule, Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; RIN 2070–AJ54. Docket # EPA–HQ–OPPT–2010–0572.

3. 2011. Executive Office of the President. Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight

of Applications of Nanotechnology and Nanomaterials. *https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf,* and Principles for Regulation and Oversight of Emerging Technologies at *https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf.*

4. 2016. EPA. Economic Analysis for the TSCA Section 8(a) Reporting Requirements for Certain Nanoscale Materials (RIN 2070–AJ54). December 2016.

5. 2012. International Organization for Standardization (ISO). Nanotechnologies—Guidance on Physicochemical Characterization for Manufactured Nano-objects Submitted for Toxicological Testing. ISO/TR (Technical Report) ISO/TR 13014:2012.

6. 1999. Colloidal Dynamics. The Zeta Potential. *http://www.colloidal-dynamics.com/docs/CDElTut1.pdf.*

7. 2013. ISO/TR. Guidelines for Characterization of Dispersion Stability. ISO/TR 13097:2013.

8. 2016. EPA. Information Submission Form. TSCA section 8(a) Information Reporting for Nanoscale Materials. EPA Form No. 7710–[tbd]; EPA ICR No. 2517.02; OMB Control No. 2070—NEW.

9. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394–6).

10. 2007. EPA. Nanoscale Materials Stewardship Program—Concept Paper.

11. OSHA. OSHA Hazard Communication Standard; 29 CFR part 1910.1200, *https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099.*

12. 2009. EPA. Interim Report on the Nanoscale Materials Stewardship Program.

13. 2015. EPA. Chemical-Specific Rules, Toxic Substances Control Act Section 8(a). OMB control No. 2070–0067 (EPA ICR No. 1198.10).

14. 2015. EPA. Addendum to an Existing EPA ICR Entitled: Chemical-Specific Rules, Toxic Substances Control Act Section 8(a). EPA ICR No. 2157.02; OMB Control No. 2070—[new].

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket. EPA prepared an economic analysis for this action (Ref. 4), which is available in the docket and discussed in Unit I.E.

B. Paperwork Reduction Act (PRA)

The information collection activities in 40 CFR part 704 related to TSCA section 8(a) reporting rules are approved by OMB under the PRA and assigned OMB control No. 2070–0067 (EPA ICR No. 1198) (Ref. 13). Because this rule revises those information collection activities and the related collection instrument, additional approval by OMB is required. As such, EPA has prepared an addendum to the currently approved ICR; the addendum is identified under EPA ICR No. 2517.02 (OMB Control No. 2070—[new]) (Ref. 14). The ICR document provides the estimated burden and costs for the information collection activities contained in this final rule. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

Respondents/affected entities: Chemical manufacturers (including importers) and processors.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 2,681.

Frequency of response: Variable.

Total estimated burden: 146,855 hours (average per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated burden cost: $11.33 million (per year), includes $0 annualized capital or operation and maintenance costs.

Change in approved burden: The total burden in OMB's inventory for the existing, approved ICR (275 hours), will be increased by 146,855 hours, for a new total burden of 147,130 hours. If an entity were to submit a report to the Agency, the annual burden is estimated to average 164 hours per response. Burden is defined in 5 CFR 1320.3(b). As presented in the economic analyses and the ICR addenda, EPA estimates that the TSCA section 8(a) rule will create a total incremental industry burden of 440,566 hours over three years.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses, small governmental jurisdictions and small non-profits. A small business exemption exists under TSCA section 8(a) reporting rules, at 40 CFR 704.5(f). For this action, EPA is modifying the exemption. EPA analyzed potential small business impacts from this rule using both the SBA employee size standards and the TSCA sales-based definition of small business. The Agency has determined that up to 411 small businesses may be impacted and evaluated the number that may incur costs at below 1% and 3%, and above 3% of sales. EPA estimates that all 411 small businesses identified will incur costs below 1% of sales, which EPA has determined is not a significant adverse economic impact on a substantial number of small entities. Details of this analysis are presented in the small entity impact analysis that EPA prepared for this action as part of the Agency's economic analysis that is in the public docket for this rule (Ref. 4).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Based on EPA's experience with proposing and finalizing rules under TSCA section 8(a), State, local and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local or Tribal government will be impacted by this rulemaking. In addition, this action will not result in annual expenditures of $100 million or more for the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk. Nevertheless, the information obtained by the reporting required by this rule will be used to inform the Agency's decision-making process regarding chemical substances to which children may be disproportionately exposed. This information will also assist the Agency and others in determining whether the chemical substances addressed in this rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This action does not affect the level of protection provided to human health or the environment. The information collected under this rule will, however, assist EPA and others in determining the potential hazards and risks associated with various chemicals manufactured processed, and used at the nanoscale. Although not directly impacting environmental justice-related concerns, this information will enable the Agency to better assess and protect human health and the environment, including in low-income and minority communities.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 704

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting requirements.

Dated: December 29, 2016.

Louise P. Wise,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 704—REPORTING AND RECORDKEEPING REQUIREMENTS

■ 1. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Add § 704.20 to Subpart B, to read as follows:

§ 704.20 Chemical substances manufactured or processed at the nanoscale.

(a) Definitions. For purposes of this section the terms below are defined as follows:

An *agglomerate* is a collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components.

An *aggregate* is a particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

Central Data Exchange or *CDX* means EPA's centralized electronic submission receiving system.

CISS tool means the Chemical Information Submission System, EPA's electronic, web-based reporting tool for the completion and submission of data, reports, and other information, or its successors.

Discrete form of a reportable chemical substance differs from another form of the same reportable chemical substance in one or more of the following 3 characteristics: (i) The change in the reportable chemical substance is due to all of the following:

(A) There is a change in process to effect a change in size, a change in one or more of the properties of the reportable chemical substances identified in paragraph (i)(C) of this definition, or both;

(B) There is a size variation in the mean particle size that is greater than 7 times the standard deviation of the mean particle size (+/− 7 times the standard deviation); and

(C) There is a change in at least one of the following properties: Zeta potential, specific surface area, dispersion stability, or surface reactivity, that is greater than 7 times the standard deviation of the measured value (+/− 7 times the standard deviation).

(ii) The reportable chemical substance has a different morphology. Examples of morphologies include but are not limited to sphere, rod, ellipsoid, cylinder, needle, wire, fiber, cage, hollow shell, tree, flower, ring, torus, cone, and sheet.

(iii) A reportable chemical substance that is coated with another chemical substance or mixture at the end of manufacturing or processing has a coating that consists of a different chemical substance or mixture.

Nanoscale Materials Stewardship Program was a program conducted by EPA from January 2008 to December 2009 under which some nanoscale material manufacturers and processors voluntarily provided EPA available information on engineered nanoscale materials that were manufactured, processed or used.

Particle is a minute piece of matter with defined physical boundaries.

Primary particles are particles or droplets that form during manufacture of a *chemical* substance before aggregation or agglomerization occurs.

Reportable chemical substance is a chemical substance as defined in section 3 of TSCA that is solid at 25 °C and standard atmospheric pressure, that is manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nm in at least one dimension, and that is manufactured or processed to exhibit unique and novel properties because of its size. A reportable chemical substance does not include a chemical substance that is manufactured or processed in a form where less than 1% of any particles, including aggregates, and agglomerates, measured by weight are in the size range of 1–100 nm.

Small manufacturer or processor means any manufacturer or processor whose total annual sales, when combined with those of its parent company (if any), are less than $11 million. The definition of *small manufacturer* in section 704.3 of this title does not apply to reporting under this section (40 CFR 704.20).

Specific surface area means the ratio of the area of the surface of the reportable chemical substance to its mass or volume. Specific surface area by mass is the ratio of the area of the surface of a nanoscale material divided by the mass (m^2/kg) and the specific surface area by volume is the area of the surface of the reportable chemical substance divided by its volume m^2/m^3.

Surface reactivity means the reactivity at the surface of a reportable chemical substance. It is dependent upon factors such as redox potential, which is a measure of the tendency of a substance to lose or acquire electrons, photocatalytic activity, including the potential to generate free radicals.

Unique and novel properties means any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance, and such properties are a reason that the chemical substance is manufactured or processed in that form or size.

Zeta potential is the electrostatic potential near the particle surface.

(b) Persons who must report. (1) Persons who can reasonably ascertain that they are manufacturers and processors of a discrete form of a reportable chemical substance during the three years prior to the final effective date of the rule must report except as provided in paragraph (c) of this section.

(2) Persons who can reasonably ascertain that they propose to manufacture or process a discrete form of a reportable chemical substance after the final effective date of the rule which was not reported under paragraph (b)(1) of this section must report except as provided in paragraph (c) of this section.

(c) When reporting is not required. (1) The following chemical substances are not subject to reporting under this section:

(i) Chemical substances formed at the nanoscale as part of a film on a surface.

(ii) DNA.

(iii) RNA.

(iv) Proteins.

(v) Enzymes.

(vi) Lipids.

(vii) Carbohydrates.

(viii) Peptides.

(ix) Liposomes.

(x) Antibodies.

(xi) Viruses.

(xii) Microorganisms.

(xiii) Chemical substances which dissociate completely in water to form ions that are smaller than 1 nanometer.

(xiv) Chemical substances that are not on the TSCA Chemical Substance Inventory at the time reporting would otherwise be required under this section.

(2) Persons who submitted a notice under 40 CFR parts 720, 721, or 723 for a reportable chemical substance on or after January 1, 2005 are not required to submit a report for the reportable chemical substance submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(3) Section 704.5(a) through (e) apply to reporting under this section. Small manufacturers and processors as defined in paragraph (a) of this section are exempt from reporting under this section.

(4) Persons who submitted some or all of the required information for a reportable chemical substance as part of the Nanoscale Materials Stewardship Program are not required to report the information previously submitted except where the person manufactures or processes a discrete form of the reportable chemical substance.

(d) What information to report. The following information must be reported for each discrete form of a reportable chemical substance to the extent that it is known to or reasonably ascertainable by the person reporting:

(1) The common or trade name, the specific chemical identity including the correct Chemical Abstracts (CA) Index Name and available Chemical Abstracts Service (CAS) Registry Number, and the molecular structure of each chemical substance or mixture. Information must be reported as specified in § 720.45.

(2) Material characteristics including particle size, morphology, and surface modifications.

(3) Physical/chemical properties.

(4) The maximum weight percentage of impurities and byproducts resulting from the manufacture, processing, use, or disposal of each chemical substance.

(5)(i) Persons described in paragraph (b)(1) of this section must report the annual production volume for the previous three years before the effective date of the final rule and an estimate of the maximum production volume for any consecutive 12-month period during the next two years of production after the final effective date of this rule.

(ii) Persons described in paragraph (b)(2) of this section must report the estimated maximum 12 month production volume and the estimated maximum production volume for any consecutive 12 month period during the first three years of production.

(iii) Estimates for paragraphs (d)(5)(i) and (ii) of this section must be on 100% chemical basis of the discrete form of the solid nanoscale material.

(6) Use information describing the category of each use by function and application, estimates of the amount manufactured or processed for each category of use, and estimates of the percentage in the formulation for each use.

(7) Detailed information on methods of manufacturing or processing.

(8) Exposure information with estimates of the number of individuals exposed in their places of employment, descriptions and duration of the occupational tasks that cause such exposure, descriptions and estimates of any general population or consumer exposures.

(9) Release information with estimates of the amounts released, descriptions and duration of the activities that cause such releases, and whether releases are directly to the environment or to control technology.

(10) Risk management practices describing protective equipment for individuals, engineering controls, control technologies used, any hazard warning statement, label, safety data sheet, customer training, or other information which is provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the substance.

(11) Existing information concerning the environmental and health effects.

(e) How to report. You must use CDX and the CISS tool to complete and submit the information required under this part to EPA electronically.

(1) *Reporting form.* You must complete EPA Form No. 7710–xx, TSCA

§ 8(a) Reporting for Nanoscale Materials: Information Submission Form.

(2) *Electronic submission.* You must submit the required information to EPA electronically via CDX and using the CISS tool.

(i) To access the CDX portal, go to *https://cdx.epa.gov.*

(ii) The CISS tool is accessible in CDX.

(f) When to report. (1) Persons specified in paragraph (b)(1) of this section must report the information specified in paragraph (d) of this section within one year after the final effective date of the rule.

(2) Persons specified in paragraph (b)(2) of this section must report the information specified in paragraph (d) of this section at least 135 days before commencing manufacture or processing of a discrete form of the reportable chemical substance, except where the person has not formed an intent to manufacture or process that discrete form at least 135 days before commencing such manufacture or processing, in which case the information must be filed within 30 days of the formation of such an intent.

(g) Recordkeeping. Any person subject to the reporting requirements of this section is subject to the recordkeeping requirements in § 704.11(a) and (b).

(h) Confidential business information. (1) Persons submitting a notice under this rule are subject to the requirements for confidential business information claims in § 704.7(a) through (c).

(2) In submitting a claim of confidentiality, a person attests to the truth of the following four statements concerning all information which is claimed confidential:

(i) My company has taken measures to protect the confidentiality of the information,

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

[FR Doc. 2017–00052 Filed 1–11–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 160219129–6999–02]

RIN 0648–BF78

List of Fisheries for 2017

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: The National Marine Fisheries Service (NMFS) publishes its final List of Fisheries (LOF) for 2017, as required by the Marine Mammal Protection Act (MMPA). The LOF for 2017 reflects new information on interactions between commercial fisheries and marine mammals. NMFS must classify each commercial fishery on the LOF into one of three categories under the MMPA based upon the level of mortality and serious injury of marine mammals that occurs incidental to each fishery. The classification of a fishery on the LOF determines whether participants in that fishery are subject to certain provisions of the MMPA, such as registration, observer coverage, and take reduction plan (TRP) requirements.

DATES: The effective date of this final rule is February 13, 2017.

ADDRESSES: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Lisa White, Office of Protected Resources, 301–427–8494; Allison Rosner, Greater Atlantic Region, 978–281–9328; Jessica Powell, Southeast Region, 727–824–5312; Penny Ruvelas, West Coast Region (CA), 562–980–4197; Lynne Barre, West Coast Region (WA/OR), 206–526–4745; Suzie Teerlink, Alaska Region, 907–586–7240; Dawn Golden, Pacific Islands Region, 808–725–5000. Individuals who use a telecommunications device for the hearing impaired may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

What is the List of Fisheries?

Section 118 of the MMPA requires NMFS to place all U.S. commercial fisheries into one of three categories based on the level of incidental mortality and serious injury of marine mammals occurring in each fishery (16 U.S.C. 1387(c)(1)). The classification of a fishery on the LOF determines whether participants in that fishery may be required to comply with certain provisions of the MMPA, such as registration, observer coverage, and take reduction plan requirements. NMFS must reexamine the LOF annually, considering new information in the Marine Mammal Stock Assessment Reports (SARs) and other relevant sources, and publish in the **Federal Register** any necessary changes to the LOF after notice and opportunity for public comment (16 U.S.C. 1387 (c)(1)(C)).

How does NMFS determine in which category a fishery is placed?

The definitions for the fishery classification criteria can be found in the implementing regulations for section 118 of the MMPA (50 CFR 229.2). The criteria are also summarized here.

Fishery Classification Criteria

The fishery classification criteria consist of a two-tiered, stock-specific approach that first addresses the total impact of all fisheries on each marine mammal stock and then addresses the impact of individual fisheries on each stock. This approach is based on consideration of the rate, in numbers of animals per year, of incidental mortalities and serious injuries of marine mammals due to commercial fishing operations relative to the potential biological removal (PBR) level for each marine mammal stock. The MMPA (16 U.S.C. 1362(20)) defines the PBR level as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population. This definition can also be found in the implementing regulations for section 118 of the MMPA (50 CFR 229.2).

Tier 1: Tier 1 considers the cumulative fishery mortality and serious injury for a particular stock. If the total annual mortality and serious injury of a marine mammal stock, across all fisheries, is less than or equal to 10 percent of the PBR level of the stock, all fisheries interacting with the stock will be placed in Category III (unless those fisheries interact with other stock(s) in which total annual mortality and serious injury is greater than 10 percent of PBR). Otherwise, these fisheries are subject to the next tier (Tier 2) of analysis to determine their classification.

Department of Occupational Safety and Health
Ministry of Human Resources
Malaysia

GUIDELINE ON CONTROL AND SAFE HANDLING OF NANOMATERIALS 2018

4.5 Atomic and molecular beam epitaxy

Atomic layer epitaxy is the process of depositing monolayers (i.e., layers one molecule thick) of alternating materials and is commonly used in semiconductor fabrication. Molecular beam epitaxy is another process for depositing highly controlled crystalline layers onto a substrate.

4.6 Dip pen lithography

A "bottom-up" method is a production process that involves depositing a chemical on the surface of a substrate using the tip of an atomic force microscope (AFM). The AFM tips are coated with the chemical, which is directly deposited on a substrate in a specific pattern.

Downstream processes use engineered nanomaterials for product application and development. Examples of these tasks or operations include weighing, dispersion/sonication, mixing, compounding/extrusion, electro-spinning, packaging, and maintenance. These activities should be evaluated for potential sources of exposure.

5. SAFETY AND HEALTH CONCERNED

The question arises on whether nanomaterials would pose any safety and health risk to humans at large. The answer would be inconclusive. Research is still being done to determine the effect of nanomaterials on humans and the environment. No definite result can be obtained as for now.

However, DOSH as an agency that looks after the safety and health of workers, must be aware of the possibility of risks imposed on the workers by handling nanomaterials. Take for example, asbestos. The effect of the material on human health was never known during the early days of usage. Not until recent years, asbestos has been proven to cause cancer and efforts are being made to control the use of asbestos.

Nevertheless, it should be clear that the purpose of this document is not to hinder or stop altogether the emergence of nanomaterials in Malaysia, but it is merely to remind those involved in handling nanomaterials regarding the possible danger imposed by the nanomaterials and the importance of taking precautionary measurements when dealing with them. **Table 1** summarize the potential hazards according to the process or task involved:

Table1: Summarize of the Potential Hazards According to the Process/Task

PROCESS / TASK	WORK ACTIVITIES	DESCRIPTIONS	EXPOSURE TO NANOMATERIALS
Production of nanomaterials	Ball milling process	Use in powder metallurgy	Nanoparticles (dry powder) in the air
	Reactor fugitive emissions	Elevated concentrations of non-CNF ultrafine releases during thermal treatment of CNFs from the reactor	Nanoparticles in high concentration
	Product harvesting	Worker put his head into the hood to brush out the product powder	Nanoparticles in high concentration
	Reactor cleaning	Manual cleaning by sweeping and vacuuming to remove residual soot	Nanoparticles
Downstream processing	Product discharge / bag filling	The off-loading of product after spray drying	Airborne nanoparticles
		Powder product is commonly discharged into a bulk tote or drum before packaging	Nanoparticles (dry powder) in high concentration
	Bag / container emptying	Workers manually open and emptying bags of solid materials	Nanoparticles (dry powder) in high concentration
	Small-scale weighing	Handling of nanomaterials / nanoparticles during scooping, pouring and dumping activities	Nanoparticles in high concentration
	Machining of products	Machining of parts that containing nanomaterials (e.g sawing, polishing, grinding)	Nanoparticles
Product packaging	Small-scale weighing / handling	Handling of nanomaterials / nanoparticles for quality assurance/ control sample	Nanoparticles
	Large-scale weighing /	Large-scale powder packing, process loading	Nanoparticles in high concentration

PROCESS / TASK	WORK ACTIVITIES	DESCRIPTIONS	EXPOSURE TO NANOMATERIALS
	handling	and tray dryer loading	
Product packaging	Product packaging	Powder product is commonly discharged into a bulk tote or drum before packaging	Nanoparticles (dry powder) in high concentration
Maintenance	Facility equipment cleaning	When cleaning dust collection systems used to capture nanoparticles such as performing fan maintenance	Liquid or solid that contains nanomaterials
	Air filter change-out	Removal of dirty air filter from a ventilation unit	
	Spill clean-up	Cleaning up spills	Liquid or solid that contains nanomaterials

5.1 Identification of Hazard

The identification of hazards is the first step in determining risk and exposure. This step involves identifying nanomaterials, and their associated processes that pose health hazards (carcinogenicity, lung inflammation, etc.), physical hazards (e.g. high levels of noise, high pressures and vacuums, strong electromagnetic flux, etc.) and physicochemical hazards (reactivity, flammability, explosivity, etc.). In a comprehensive hazard identification process, all potential occupational hazards, including workplace chemicals should be identified in this step, including hazards that are low-level hazards or of low exposure potential, or hazards already being controlled in the workplace.

In order to identify hazards, information can be obtained generally from many sources including Safety Data Sheets (SDS), International Chemical Safety Cards (ICSC), publications from trade associations or government authorities, test data or proprietary information. For many nanomaterials there is currently a lack of specific knowledge of potential health effects, and exposure limits have not been established. Consequently these sources may not be able to provide sufficient information in order to adequately report the hazards associated with a specific engineered nanomaterial. The quality of information in some SDS has been reported as an issue, as has the lack of available SDS for some nanomaterials. If data are not available, then it may be possible to generate data through the testing of specific high-priority nanomaterials.

To understand and identify the hazards of the nanomaterials, the information about similar materials can be used. In this case, it is important to make sure that the information been used is truly applicable to the corresponding nanomaterial such as, carbon nanotubes (CNTs) and carbon nanofibres (CNF).

Many of the most commonly used nanomaterials have similar or the same chemical composition as larger scale particulates (often referred to as bulk materials). However, it is not clear which properties from a bulk material can be assumed to apply to a nano sized particulate.

In addition, the many differences between nanomaterials means that it is often not clear which properties of a nano sized particulate can be assumed to apply to other nano sized particulates. It is therefore important to consider 'sameness' when using information on one material to establish the hazardous properties of another material.

To determine the similarities and differences between different nanomaterials, it is important to obtain as much information as possible on the physical and chemical characteristics of each. It is suggested as a minimum that the following characteristics could be used to establish 'sameness':

- Chemical composition and purity
- Particle size distribution. Specialist advice from the supplier or an expert in the field of nano characterisation may be seek to make sure that the particle size distribution information is suitable for the current situation.
- Surface functionalization / treatment
- Shape
- Surface area

The greater the differences between the physical and chemical characteristics of one material and another, even though they may have the same chemical composition, the more likely it is that hazard data for one material will not provide a suitable basis to assess the hazards of another. It is therefore important to have information on the physical and chemical characteristics of the material been used, in order to identify materials with similar characteristics that may have similar hazards. If the hazard data cannot properly establish the identity and characteristics of the material that has been tested, it is unwise to assume that the results are applicable to the nanomaterial.

5.1.1 Physicochemical hazard

The field of nanotechnology is relatively new, and therefore little is known about the potential occupational safety hazards that may be associated with engineered nanomaterials. However, the information that is available about the properties of nanoparticles indicates that under given conditions, engineered nanomaterials may pose dust explosion hazard and be spontaneously flammable when exposed to air because of their large surface area and overall small size. Processes that generate engineered nanomaterials in the gas phase or use or produce nanomaterials as powders, slurries, suspensions, or solutions, are likely to release nanoparticles into the air and therefore create the greatest risk for fire and explosion. Currently, the primary safety concerns associated with nanomaterials in the workplace are fire and explosion.

Some nanomaterials are designed specifically to generate heat through the progression of reactions at the nanoscale; this too may present a fire hazard that is unique to engineered nanomaterials.

The ability of nanomaterials to become electrostatically charged during transport, handling, and processing introduces a unique explosion hazard when dealing specifically with nanopowders. Their tendency to charge has been found to drastically increase as particle surface area increases. As a result, their large surface area may become highly charged and become their own ignition source if the powder is dispersed in the air.

Nanoparticles and nanostructured porous materials have been used for many years as effective catalysts for increasing the rate of reactions or decreasing the necessary temperature for reactions to occur in liquids and gases. Depending on their composition and structure, some nanomaterials may initiate catalytic reactions and increase the fire and explosion potential that would not otherwise be anticipated from their chemical composition alone.

5.1.2 Health hazards

The toxicity of nanoparticles may be affected by different physicochemical properties, including size, shape, chemistry, surface properties, agglomeration, biopersistence, solubility, and charge, as well as effects from attached functional groups and crystalline structure. The greater surface-area-to-mass ratio of nanoparticles makes them generally more reactive than their macro sized counterparts. These properties are the same ones that make nanomaterials unique and valuable in manufacturing many products. Currently, the toxicity of many nanomaterials is unknown, but initial research indicates that there may be health concerns related to occupational exposures.

5.2 Safety and Health Effect

The potential health risk following exposure to a substance is generally associated with the magnitude and duration of the exposure, the persistence of the material in the body, the inherent toxicity of the material, and the susceptibility or health status of the person exposed. More data are needed on the health risks associated with exposure to engineered nanomaterials. Results of existing studies in animals and humans on exposure and response to ultrafine or other respirable particles provide a basis for preliminary estimates of the possible adverse health effects from exposures to similar engineered materials on a nanoscale. NIOSH has published Recommended Exposure Limits (REL) of three nanomaterials, namely ultrafine titanium dioxide (TiO_2) at 300 µg/m^3 (NIOSH, 2011) and carbon nanotubes (CNTs) plus carbon nanofibers (CNFs) at 1.0 µg/m^3 (NIOSH, 2013).

Experimental studies in rodents and cell cultures have shown that the toxicity of ultrafine or nanoparticles is greater than that of the same mass of larger particles of similar chemical composition (Oberdörster et al., 1992, 1994a,b; Lison et al., 1997; Tran et al., 1999, 2000; Brown et al., 2001; Duffin et al., 2002; Barlow et al. 2005). In addition to particle surface area, other particle characteristics may influence toxicity, including surface functionalisation or coatings, solubility, shape, and the ability to generate oxidant species and to adsorb biological proteins or bind to receptors (Duffin et al. 2002; Oberdörster et al. 2005a; Maynard and Kuempel 2005; Donaldson et al. 2006). More research is needed on the influence of particle properties on interactions with biological systems and the potential for

adverse effects. International research strategies for evaluating the safety of nanomaterials are actively being developed through cooperative efforts (Thomas et al. 2006).

Exposure to nanomaterials may occur through inhalation, dermal contact, or ingestion depending on how personnel use and handle them. The full health effects of exposures to nanomaterials are not fully understood at this time. For example, a peer-reviewed toxicity study on CNTs indicated that the toxicity of nanoparticles depends on specific physiochemical and environmental factors and thus the toxic potential of each nanoparticle needs to be evaluated separately (Helland et al., 2007). Results of existing studies in animals or humans provide some basis for preliminary estimates of areas of concern (Stanford University, 2009). Studies to date have indicated:

- Increased toxicity of ultrafine particles or nanoparticles as compared to larger particles of similar composition. Chemical composition and other particle properties can also influence toxicity (Oberdörester et al., 1992, 1994a,b, 2005a; Lison et al., 1997; Tran et al., 1999, 2000; Brown et al., 2001; Duffin et al., 2002; Barlow et al. 2005; Maynard and Kuempel 2005; Donaldson et al. 2006).
- A greater proportion of inhaled nanoparticles will deposit in the respiratory tract as compared to larger particles (ICRP 1994; Jaques and Kim 2000; Daigle et al. 2003; Kim and Jaques 2004).
- Nanoparticles can cross cell membranes and interact with sub cellular structures where they have been shown to cause oxidative damage and impair function of cells in culture.
- Nanoparticles may be capable of penetrating healthy intact skin and translocating to other organ systems following penetration (Takenaka et at. 2001; Kreyling et al 2002; Oberdörester et al. 2002, 2004; Semmler et al. 2004; Geiser et al. 2005).
- Catalytic effects and fire or explosion are other hazards to consider (Pritchard 2004).

5.3 Nanomaterial Risk Assessment (NaRA)

Nanomaterial risk assessment means the process of evaluating the risk to safety and health arising from hazards at work. Risk is the determination of likelihood and severity of the credible accident or event sequences in order to determine magnitude and to priorities identified hazards. It can be done by qualitative, quantitative or semi quantitative method.

Risk can be presented in variety of ways to communicate the results of analysis to make decision on risk control. For risk analysis that uses likelihood and severity in qualitative method, presenting result in a risk matrix is a very effective way of communicating the distribution of the risk throughout a plant and area in a workplace. Risk can be calculated using the following formula:

Risk = Likelihood x Severity

Risk also been defined as a probability of over exposure and the consequences of the exposure. This is so because of potentially toxic chemical may cause death or serious health effect if the exposure is substantial. Therefore the risk equation can also be defined as:

Risk = Hazard x Exposure

Assessment of health risks arising from exposure to nanomaterials or other substances requires understanding of the intrinsic toxicity of the substance, the levels of exposure (by inhalation, by ingestion or through the skin) that may occur and any relationship between exposure and health effects.

Risk assessment for nanomaterials can be carried out by using control banding method. The following control banding method is based on the method outlined by the COSHH Essential and GoodNanoGuide that can be used to guide the industries on the matters pertaining to nanomaterials.

The example of methodologies being used for conducting risk assessment listed in Appendix 2 and 3.

5.3.1 Steps to conduct assessment

Steps to conduct NaRA is summarized as the following process flowchart:

Figure 4: NaRA Process Flowchart

Step 1: Gather information and identify material

Identify areas that have nanomaterials related activities. The areas involved should be specified for control banding purposes. Information of the material can be obtained, but not limited to these documents:

a) Chemical/Material register;
b) Safety Data Sheet (SDS) or other material information;
c) Label;
d) Information about the task where chemical/material is used and total duration of use;
e) Existing control measures such as general ventilation, local exhaust ventilation and etc;
f) Other information such as layout plan, process flow, operating temperature of process and number of workers exposed to chemical/material.

Step 2: Determine the degree of release

The potential for exposure is described through the state of the nanomaterial as shown in **Table 2**.

Table 2: State of the Nanomaterial

State of the nanomaterial	Description
Bound	• Nanoparticles in solid matrix. • Nanoparticle dispersed and fixed within a polymer matrix, incapable, as a practical matter, of becoming airborne.
Potential	• Nanoparticles in friable or sol gel matrix.
Free/Unbound	• Nanoparticles unbound, not aggregated, not contained within a matrix that would be expected to prevent the nanoparticles from being separate-ly mobile and a potential source of exposure. • Particle suspended as an aerosol or in a liquid.

Step 3: Determine exposure duration

Exposure duration is categorised into short, medium and long based on duration of exposure to nanomaterials as specified in **Table 3**. Duration of exposure must consider work activities or processes involving exposure to nanomaterials.

Table 3: Exposure Duration

Category	Description
Short	< 4 hours/day, 2 days/week
Medium	4 to 6 hours/day, 3 to 5 days/week
Long	6 to >8 hours/day, 3 to 5 days/week

Step 4: Determine hazard group

Nanomaterials are grouped into three hazard groups:

Table 4: Hazard Group

Category	Description
A	Known to be inert
B	Understand reactivity and function
C	Unknown properties

Step 5: Determine control band (risk level)

Determine the risk level or control band using **Table 5**.

Table 5: Control Matrix

Degree of Release / Exposure Duration	Bound Materials	Potential Release	Free / Unbound
Hazard Group A (Known to be inert)			
Short	1	1	2
Medium	1	1	2
Long	1	2	2
Hazard Group B (Understand reactivity/function)			
Short	1	2	2
Medium	1	2	3
Long	1	3	3
Hazard Group C (Unknown properties)			
Short	2	2	3
Medium	2	3	4
Long	2	4	4

Control Band (Risk Level) Key

Band	Control Measures
1	General ventilation and personal protective equipment (PPE)
2	Engineering controls and/or respirators, additional PPE
3	Containment (e.g. glove box)
4	Seek specialist advice

Step 6: Develop and implement action plan

Employer should develop action plan to control the exposure of nanomaterials based on the control band obtained. Refer to paragraph 5.4 for further details.Take account of any safety hazards (refer to advice on the SDS or any related safety information), which may affect the required controls and their implementation.

Consider additional actions required to fully comply with other legislation requirements and other recommended control measures. For example nanomaterials which are chemicals hazardous to health in the workplace should be referred to Occupational Safety and Health (Use and Standards of Exposure to Chemicals Hazardous to Health) Regulations 2000.

The measures, procedures, and equipment necessary to control any accidental emission of chemical hazardous to health as a result of leakage, spillage, or process or equipment failure should also be considered.

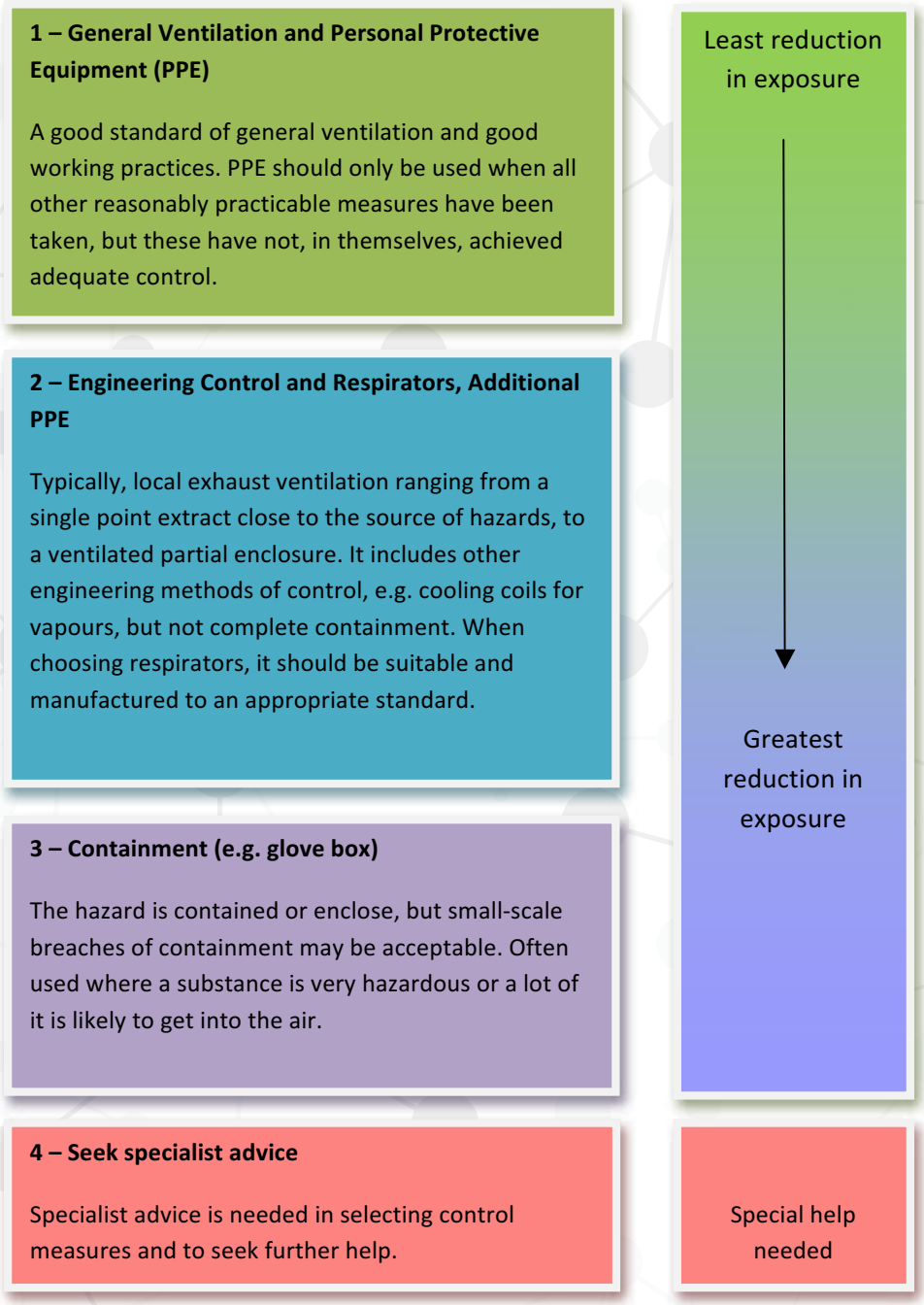
The development and implementation of the action plan should include the participation of employees. Employer should check the effectiveness of the control measures periodically.

Step 7: Report writing and record keeping

Assessments done should be documented properly and maintained for future reference. They can either be in hard copies (for example bound reports) or electronic copies. All records should be stored and maintained in such a way that they are readily retrievable and protected against damage, deterioration or loss.

5.4 CONTROL MEASURES

The four approaches are:



5.4.1 General ventilation

This control measures applied to assessment which results in Band 1. It is a control of the contaminants generated in a space by diluting it with uncontaminated outside air flowing into the room in large quantities so as to reduce the concentration of air contaminants to acceptable levels. There are two types of general or dilution ventilations, i.e. natural ventilation and forced ventilation.

Natural ventilation

- Produced by movement of air entering and leaving through the openings such as by opening of windows or doors to allow air to exchange naturally.
- Should not be used as control measures to reduce workers exposure in a workroom.

Forced ventilation

- There are three types of mechanically induced air movement used to dilute contaminant
  - i) supply system
  - ii) exhaust system
  - iii) supply-exhaust system

- Use of mechanical fan e.g. axial fan to move air out of space for the purpose of diluting the contaminants in the space.

Figure 5: Industrial axial fan

5.4.2 Engineering control

This control measures applied to assessment which results in Band 2. Methods of control that apply engineering principles such as local exhaust ventilation, cooling coil for vapours, water spray, etc. are also highly encouraged to eliminate or minimise the risk of exposure to nanomaterials.

Local Exhaust Ventilation (LEV) is a system that consists of hood, duct, air cleaner/filter, exhaust fan e.g. centrifugal fan and exhaust stack to capture or remove contaminant at/near source or point of release for example fume cupboard, spray booth, etc.

5.4.3 Containment

This control measures applied to assessment which results in Band 3. The hazard is contained or enclosed due to the very hazardous nature of the nanomaterials. It is a closed system with limited breach of containment.

5.4.4 Seek special advice

This control measures applied to assessment which results in Band 4. Seek special advice means a situation where more specific and specialist advice needed. The advice may come from an expert such as:

- qualified occupational hygienist;
- professional engineer; or
- subject matter expert of nanomaterials.

These experts can give site-specific advice on risk assessment, the possibility of substituting the nanomaterials for a less hazardous materials, and suitable control measures.

5.5 Personal protective equipment (PPE)

PPE is used to complement other control measures for added precaution. Protective equipment only protects the person wearing it, not anyone else. This also needs checking and maintenance because if it fails it no longer provides protection and exposes the wearer to the hazard. Users need to know exactly how to use and store their PPE correctly as do supervisors. Employer should train their workers on proper use of PPE. Selection of PPE should be done based on the possible routes of exposure of nanomaterials. For example, respiratory protection for inhalation, protective clothing for skin and eyes.

5.5.1 Protective clothing

Protective clothing is attire that covers the whole body such as lab coats, long pants and shoes should be worn to avoid incidental exposures of nanomaterials to skin. Non-woven materials are also preferred as the intertwined fibres can avoid nanomaterials penetration. Lab coats that are made out of non-woven materials are recommended to be worn when handling nanomaterials.

For some situations (low hazard material, low exposure risk), use of cotton or cotton-polyester lab coats or coveralls may provide sufficient protection.

For higher risk scenarios (high hazard material or high nanomaterials exposure potential), protective clothing should be made from a low dust-retention/low dust-release fabric. Nonwoven textiles (e.g. high-density/airtight polyethylene) can provide a high level of protection. Avoid protective clothing made of paper, wool, cotton, or other woven fabrics (e.g. polyester) for handling materials of high concern. Common types of protective clothing for powder handling include a lab coat, long sleeves without cuffs, long pants without cuffs, coveralls, closed-toe shoes made of low-permeability material, and shoe covers.

When a high level of protection is needed, consider using protective clothing with a hood. Interfaces between chemical protective clothing and respirator, protective footwear covering, and gloves can be sealed with tape to increase protection.

However, you must make provision for clean overalls/lab coats to be put on and dirty ones removed in a manner that does not contaminate individuals or the general workplace. If reusable lab coats or overalls are used you must consider their laundering and prevention of secondary exposure. (In the event of a 'one-off' gross contamination, consider treating even 'reusable' PPE as disposable.)

How often they need to be changed and laundered will depend on the type of task. As a minimum, it is suggested that lab coats should be changed at least once a month. Do not allow work wear to be taken home for laundering.

5.5.2 CNTs and other biopersistent High Aspect Ratio Nanomaterials (HARNs)

For CNTs and other biopersistent HARNs, protective clothing made of materials such as polyethylene textiles (eg Tyvek) performs better than a standard lab coat as this type of material does not retain dust or allow dust to penetrate, and can be disposable. Wool, cotton poly-cotton or knitted material, which can retain dust, is not recommended.

Nanomaterials can permeate through some intact disposable overall materials and by implication woven reusable materials (European Nanosafe). Non-woven Tyvek/Tychem polyethylene overalls are recommended for use with nanomaterials, rather than paper or cotton.

Figure 6: Tychem

Figure 7: Tyvec

5.5.3 Gloves

Use suitable disposable single-use gloves manufactured to an appropriate standard. Glove material thickness is a major issue in determining diffusion of nanomaterials and this should be considered in the risk assessment. If the risk assessment indicates latex is the safest choice, then only use low-protein powder-free gloves.

Other substances which may be involved during the nanomaterial handling process, e.g. solvents, must be considered in choosing gloves material. Employees should be properly trained in how to put on and remove gloves without contaminating themselves.

Figure 8: The incorrect (left) and the correct way (right) to wear glove (NIOSH UK, 2012)

5.5.4 Eye protection

Use of suitable eye protection is recommended when handling any chemicals, this includes all nanomaterials. A minimum of close fitting safety glasses should be used for all nanomaterials.

5.5.5 Respiratory protective equipment (RPE)

When choosing RPE it should be suitable and manufactured to an appropriate standard. Also consider any other chemicals, e.g. solvents, which may be used when handling nanomaterials. Check with RPE supplier for the most suitable filter.

When RPE is used as a secondary control for emergencies or accidental spillages or where additional protection is required as indicated by the risk assessment, disposable and half-masks should have an assigned protection factor (APF) of no less than 20.

When RPE is used as a primary control, i.e. the only method of control (not recommended unless no other method available), use a full-face with mask with APF 40, preferably powered if used for over one hour.

All types of masks (including disposable) must be suitable for the task and face-fitted for the individual by a competent face-fit tester. Employees should be properly trained in RPE use and supervised. If the equipment is reusable, it should be regularly cleaned and checked to ensure that it remains effective. Written records of RPE maintenance must be kept.

5.5.6 Other recommended control measures

5.5.6.1 Elimination

Elimination is definitely not a favourable option to be considered by the industries as nanomaterials are very lucrative products that can improve the quality of life. As long as there is no solid evidence of nanomaterials being harmful to humans and the environment, nanomaterials will continue to be developed, produced and used widely.

5.5.6.2 Substitution

Substitution on the other hand, can be applied to the process of producing nanomaterials. Different method and mechanical or chemical process can be opted for instead of using hazardous method or chemicals to produce nanomaterials.

5.5.6.3 Isolation

Isolation of processes involving nanomaterials are currently the most practiced form of control. Most of the equipment used for producing nanomaterials is made with built in isolation features. Other than that, the use of gloveboxes as isolation tools is also encouraged during handling of nanomaterials.

5.5.6.4 Administrative control

Other than that, the application of administrative control through the compliance to safe operating procedures (SOP) by all workers should also be implemented. An example of this is outlined in the Nanotoolkit developed by California Nanosafety Consortium of Higher Education. Although the Nanotoolkit is focused on academic research setting, the concept of developing an SOP for a specific task brought forward by Nanotoolkit can be adopted. Workers must also be given enough training to ensure correct handling, storage and disposal of the nanomaterials.

5.5.5.6 Cleaning spillages

All equipment used and the workplace must be thoroughly cleaned by using the wet-wipe method after each use of in case of spillage. It is prohibited to brush, use compressed air or standard vacuum cleaner for any cleaning purposes.

A dedicated commercial HEPA-filtered cleaner with the filter regularly changed can be used for cleaning purposes but caution should be taken especially when disposing of the used filter. The used filter should be treated as hazardous waste and disposed accordingly using precautionary approach.

Emergency procedures should be in place to deal with spills, accidents and emergencies.

5.5.6.6 Signage in the workplace for nanomaterials

Workplaces with nanomaterials should be posted with safety signs which indicates the use of nanomaterials at that area and usage of suitable PPE with the addition of any relevant and specific information on any actual or potential hazards of the specific nanomaterial handled.

Appropriate hazard labels, signs or pictograms should be selected based on the hazard information available regarding the material. Precautionary approach should be adopted if no specific information is available.

5.6 Remove, Reuse, Disposal of Nanomaterials

Waste nanomaterials classified as 'hazardous waste' must be disposed of in a safe and appropriate manner. For further information, please refer to specific requirement by relevant authorities (i.e. Department of Environment).

Procedures for removing PPE, including sequence and technique, should be tailored to the specific combination of PPE worn and level of PPE contamination to prevent exposing the worker or contaminating the work area. Used PPE should be removed carefully in the designated area. Workers wearing potentially contaminated PPE should avoid touching surfaces that will be touched by others not wearing PPE. The worker should avoid skin contact with contaminated PPE surfaces and avoid stretching and 'snapping' gloves or elastic cuffs/closures to prevent release of nanomaterials contamination into the air or onto other surfaces. When respirators are worn they should be removed after other outer PPE. An example sequence of PPE removal follows:

1. Remove disposable outer gloves. Allow first glove to turn inside out as it is being slowly removed; hold it in double-gloved hand then remove other hand's outer glove turning it inside out and pulling it over the first glove removed to contain it as if in a 'bag'. Discard into waste receptacle.
2. Remove goggles and place into cleaning receptacle, as needed.
3. Remove lab coat. If known to be contaminated, turn it inside out as it is removed, gently fold in on itself to keep contamination contained, and deposit into waste or laundry receptacle.
4. Remove respirator and place into waste or cleaning receptacle.
5. Remove inner gloves (as in #1 above), discard, and then wash hands and forearms.

For PPE (e.g. lab coats or coveralls) that will be reused, secondary exposure must be addressed prior to, and during, cleaning or laundering. A lab coat with no suspected or visible contamination that will be reused should be hung on an individual hook so the outside of one coat does not contaminate the inside of another. For disposable items, ensure that contaminated PPE is properly disposed. If gross contamination of reusable PPE occurs, consider disposal rather than cleaning. Secondary contamination from used PPE may be prevented (whether prior to laundering or disposal) by collecting items in an appropriately labelled plastic bag or other sealable container as they are removed. Workers should be educated on methods and practices to prevent them from inadvertently taking nanomaterials contamination home.

GLOSSARY

Terms	Definition
Nanofibre	A nanomaterial with two external dimensions at the nanoscale with a nanotube defined as a hollow nanofibre and a nanorod as a solid nanofibre
Nanoparticle	A nanomaterial with all three external dimensions at the nanoscale
Nanoaerosol	Nanomaterial may be suspended in a gas
Nanocomposite	Nanomaterial may be embedded in a matrix
Ultrafine particles	Nanometre diameter particles that have not been intentionally produced but are the incidental products of processes involving combustion, welding, or diesel engines
CNT	Carbon nanotubes
CNF	Carbon nanofibres

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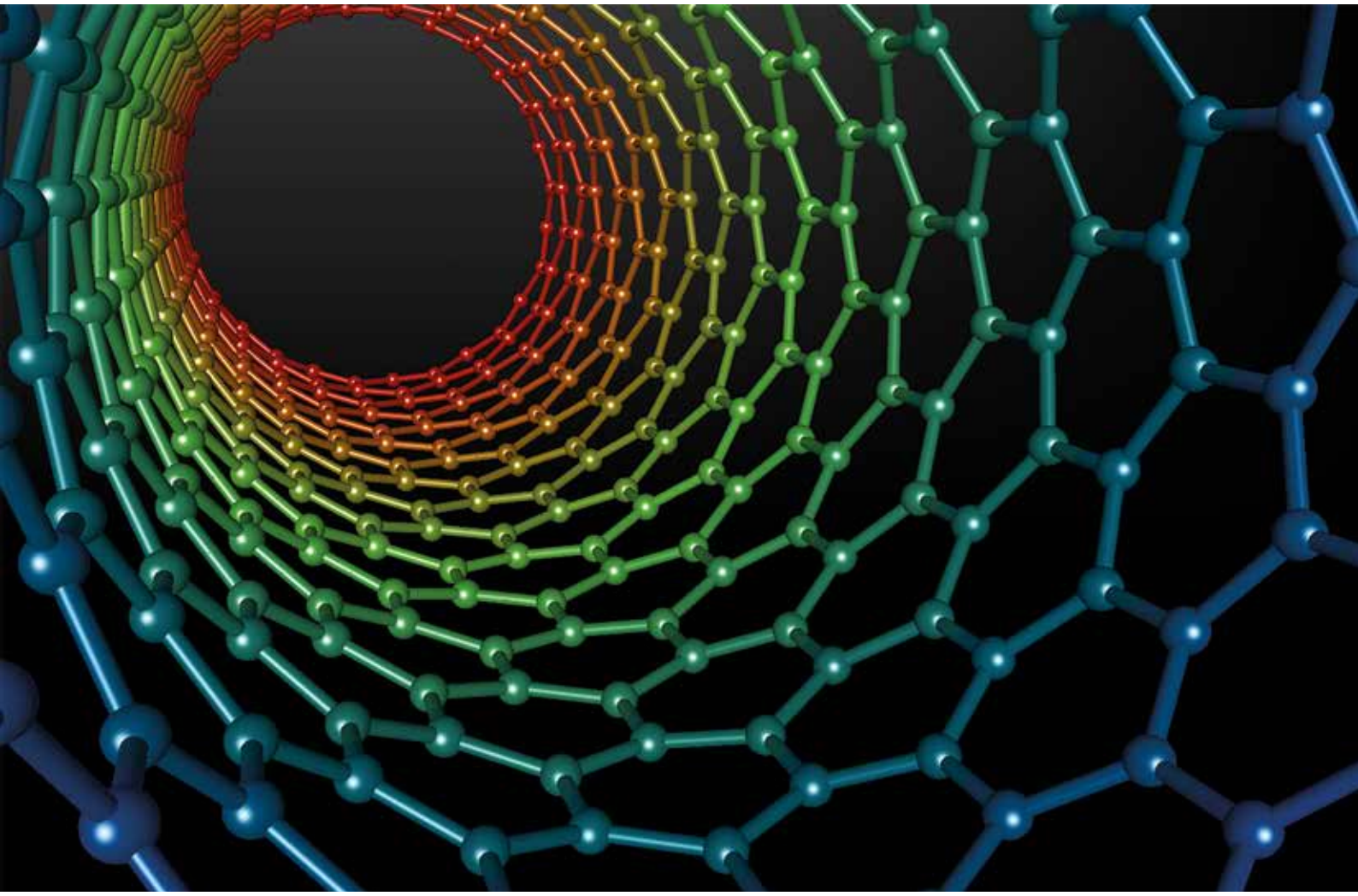
51. http://www.ibar.dk
52. http://nanoparticlelibrary.net/

ANNEXURE A9

WHO GUIDELINES ON PROTECTING WORKERS FROM POTENTIAL RISKS OF MANUFACTURED NANOMATERIALS



World Health Organization

EXECUTIVE SUMMARY

The term nanomaterials refers to materials that have at least one dimension (height, width or length) that is smaller than 100 nanometres (10^{-7} metre), which is about the size of a virus particle. This particular size dimension represents a major characteristic of manufactured nanomaterials (MNMs). The unique properties of MNMs may result in highly desirable behaviour leading to such varying applications as better paints, better drugs and faster electronics. However, for the same reason, MNMs may also present health hazards that differ from those of the substance in bulk form, and may require different test methods for hazard, exposure and risk assessment from their bulk material counterparts.

The toxicity of MNMs may largely depend on numerous physicochemical properties, including size, shape (i.e. size in a particular dimension), composition, surface characteristics, charge and rate of dissolution. There is currently a paucity of precise information about human exposure pathways for MNMs, their fate in the human body and their ability to induce unwanted biological effects such as generation of oxidative stress. Data from in vitro, animal and human MNM inhalation studies are available for only a few MNMs. So far, no long-term adverse health effects in humans have been observed. This could be due to the recent introduction of MNMs, the precautionary approach to avoid exposure and ethical concerns about conducting studies on humans. This means that, except for a few materials where human studies are available, health recommendations must be based on extrapolation of the evidence from in vitro, animal or other studies from fields that involve exposure to nanoscale particles, such as air pollution, to the possible effects in humans.

The increased production of MNMs and their use in consumer and industrial products means that workers in all countries will be at the front line of exposure to these materials, placing them at increased risk for potential adverse health effects.

Therefore, the World Health Organization (WHO) has developed these guidelines with recommendations on how best to protect workers from the potential risks of MNMs. The recommendations are intended to help policy-makers and professionals in the field of occupational health and safety in making decisions about the best protection against potential risks specific to MNMs in workplaces. These guidelines are also intended to support workers and employers. However, they are not intended as a handbook or manual for safe handling of MNMs in the workplace because this requires addressing more general occupational hygiene issues beyond the scope of these guidelines.

GUIDING PRINCIPLES

The Guideline Development Group (GDG) used a precautionary approach as one of its guiding principles. This means that exposure has to be reduced, despite uncertainty about the adverse health effects, when there are reasonable indications to do so.

In addition, the hierarchy of controls was an important guiding principle. This means that when there is a choice between control measures, those measures that are closer to the root of the problem should always be preferred over measures that put a greater burden on workers, such as the use of personal protective equipment (PPE).

BEST PRACTICE

The GDG considers the following to be best practice in preventing the adverse health effects of MNMs:

- Group nanomaterials into MNMs with specific toxicity, MNMs that are fibres and MNMs that are granular biopersistent particles.
- Educate and train workers in the specific health and safety issues of MNMs.
- Involve workers in all phases of risk assessment and control.

METHODS

For all important issues, systematic reviews of the current state of the science were commissioned to inform the recommendations according to the process set out in the *WHO Handbook for guideline development*. The recommendations were rated as "strong" or "conditional" depending on the quality of the scientific evidence, values and preferences, and costs related to the recommendation. All recommendations were made based on consensus within the GDG.

RECOMMENDATIONS

A. Assess health hazards of MNMs

1. The GDG recommends assigning hazard classes to all MNMs according to the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals for use in safety data sheets. For a limited number of MNMs this information is made available in these guidelines (*strong recommendation, moderate-quality evidence*).
2. The GDG recommends updating safety data sheets with MNM-specific hazard information or indicating which toxicological end-points did not have adequate testing available (*strong recommendation, moderate-quality evidence*).
3. For the respirable fibres and granular biopersistent particles' groups, the GDG suggests using the available classification of MNMs for provisional classification of nanomaterials of the same group (*conditional recommendation, low-quality evidence*).

B. Assess exposure to MNMs

4. The GDG suggests assessing workers' exposure in workplaces with methods similar to those used for the proposed specific occupational exposure limit (OEL) value of the MNM (*conditional recommendation, low-quality evidence*).
5. Because there are no specific regulatory OEL values for MNMs in workplaces, the GDG suggests assessing whether workplace exposure exceeds a proposed OEL value for the MNM. A list of proposed OEL values is provided in Annex 1 of these guidelines. The chosen OEL should be at least as protective as a legally mandated OEL for the bulk form of the material (*conditional recommendation, low-quality evidence*).
6. If specific OELs for MNMs are not available in workplaces, the GDG suggests a stepwise approach for inhalation exposure with, first an assessment of the potential for exposure; second, conducting basic exposure assessment and third, conducting a comprehensive exposure assessment such as those proposed by the Organisation for Economic Co-operation and Development (OECD) or Comité Européen de Normalisation (the European Committee for Standardization, CEN) (*conditional recommendation, moderate-quality evidence*). For dermal exposure assessment, there was insufficient evidence to recommend one method of dermal exposure assessment over another.

C. Control exposure to MNMs

7. Based on a precautionary approach, the GDG recommends focusing control of exposure on preventing inhalation exposure with the aim of reducing it as much as possible (*strong recommendation, moderate-quality evidence*).
8. The GDG recommends reduction of exposures to a range of MNMs that have been consistently measured in workplaces especially during cleaning and maintenance, collecting material from reaction vessels and feeding MNMs into the production process. In the absence of toxicological information, the GDG recommends implementing the highest level of controls to prevent workers from any exposure. When more information is available, the GDG recommends taking a more tailored approach (*strong recommendation, moderate-quality evidence*).
9. The GDG recommends taking control measures based on the principle of hierarchy of controls, meaning that the first control measure should be to eliminate the source of exposure before implementing control measures that are more dependent on worker involvement, with PPE being used only as a last resort. According to this principle, engineering controls should be used when there is a high level of inhalation exposure or when there is no, or very little, toxicological information available. In the absence of appropriate engineering controls PPE should be used, especially respiratory protection, as part of a respiratory protection programme that includes fit-testing (*strong recommendation, moderate-quality evidence*).
10. The GDG suggests preventing dermal exposure by occupational hygiene measures such as surface cleaning, and the use of appropriate gloves (*conditional recommendation, low-quality evidence*).

11. When assessment and measurement by a workplace safety expert is not available, the GDG suggests using control banding for nanomaterials to select exposure control measures in the workplace. Owing to a lack of studies, the GDG cannot recommend one method of control banding over another (*conditional recommendation, very low-quality evidence*).

D. Health surveillance

The GDG cannot make a recommendation for targeted MNM-specific health surveillance programmes over existing health surveillance programmes that are already in use owing to the lack of evidence.

E. Training and involvement of workers

The GDG considers training of workers and worker involvement in health and safety issues to be best practice but cannot recommend one form of training of workers over another, or one form of worker involvement over another, owing to the lack of studies available.

It is expected that there will be considerable progress in validated measurement methods and risk assessment. Therefore, the GDG proposes to update these guidelines in five years' time, in 2022.

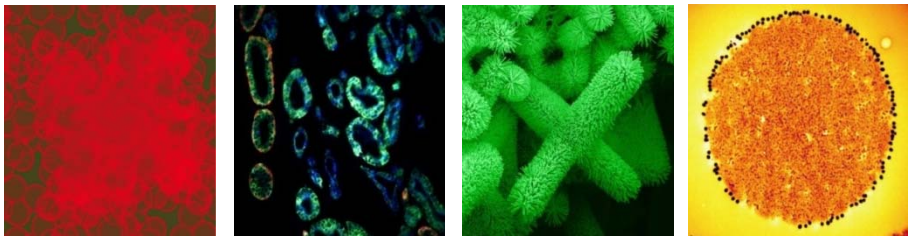
ANNEXURE A10
84

U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

EPA Needs to Manage Nanomaterial Risks More Effectively

Report No. 12-P-0162 **December 29, 2011**



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12-P-0162
December 29, 2011

U.S. Environmental Protection Agency
Office of Inspector General

At a Glance

Why We Did This Review

The purpose of this review was to determine how effectively the U.S. Environmental Protection Agency (EPA) is managing the human health and environmental risks of nanomaterials.

Background

Nanomaterials are currently used in a wide variety of applications, including consumer products, health care, transportation, energy, and agriculture. The Agency considers nanomaterials as chemical substances that are controlled at the scale of approximately one-billionth of a meter. EPA has the authority, through several environmental statutes, to regulate nanomaterials. Although the development of nanomaterials and nanomaterial-enhanced products is expanding rapidly, the health implications of nanomaterials have not yet been determined.

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2012/20121229-12-P-0162.pdf

EPA Needs to Manage Nanomaterial Risks More Effectively

What We Found

We found that EPA does not currently have sufficient information or processes to effectively manage the human health and environmental risks of nanomaterials. EPA has the statutory authority to regulate nanomaterials but currently lacks the environmental and human health exposure and toxicological data to do so effectively. The Agency proposed a policy under the Federal Insecticide, Fungicide, and Rodenticide Act to identify new pesticides being registered with nanoscale materials. After minimal industry participation in a voluntary data collection program, the Agency has proposed mandatory reporting rules for nanomaterials under the Federal Insecticide, Fungicide, and Rodenticide Act, and is also developing proposed rules under the Toxic Substances Control Act.

However, even if mandatory reporting rules are approved, the effectiveness of EPA's management of nanomaterials remains in question for a number of reasons:

- Program offices do not have a formal process to coordinate the dissemination and utilization of the potentially mandated information.
- EPA is not communicating an overall message to external stakeholders regarding policy changes and the risks of nanomaterials.
- EPA proposes to regulate nanomaterials as chemicals and its success in managing nanomaterials will be linked to the existing limitations of those applicable statutes.
- EPA's management of nanomaterials is limited by lack of risk information and reliance on industry-submitted data.

These issues present significant barriers to effective nanomaterial management when combined with existing resource challenges. If EPA does not improve its internal processes and develop a clear and consistent stakeholder communication process, the Agency will not be able to assure that it is effectively managing nanomaterial risks.

What We Recommend

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop a process to assure effective dissemination and coordination of nanomaterial information across relevant program offices. The Agency agreed with our recommendation and provided a corrective action plan with milestone dates. This recommendation is open with agreed-to actions pending.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

December 29, 2011

MEMORANDUM

SUBJECT: EPA Needs to Manage Nanomaterial Risks More Effectively
Report No. 12-P-0162

FROM: Arthur A. Elkins, Jr.
Inspector General

TO: Jim Jones
Acting Assistant Administrator for Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

Because you have provided a corrective action plan with milestone dates, you are not required to provide a written response to this report. Should you choose to provide a response, your response will be posted on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal. We have no objections to the further release of this report to the public. We will post this report to our website at http://www.epa.gov/oig.

If you or your staff have any questions, please contact Wade Najjum at (202) 566-0827 or najjum.wade@epa.gov; Jeffrey Harris at (202) 566-0831 or harris.jeffrey@epa.gov; or Lauretta Joseph, Project Manager, at (212) 637-3049 or ansah.lauretta@epa.gov.

Gmail **sravan kumar <advsravan@gmail.com>**

Affidavit by Interveners in OA No. 66 of 20217

1 message

sravan kumar <advsravan@gmail.com> Thu, Nov 25, 2021 at 10:59 PM
To: Madhuri Reddy <reddymadhuri09@gmail.com>, Yogeshwaran Amarneethi <yogeshwaranadv@gmail.com>, Sarashwathy Meyappan <advocatesarashwathy@gmail.com>, judicial-ngtsz@gov.in

Madam and Sir

Kindly find the attached Additional Affidavit along with documents in the above mentioned case.

Kindly acknowledge the receipt of the same.

with regards

Sravan Kumar
Advocate for the Interveners
9811237009

Affidavit 25.11.2021.pdf
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