ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2009–0206; FRL–8425–6]

Sixty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its 64th report to the Administrator of EPA on June 25, 2009. In the 64th ITC report, which is included with this notice, the ITC has no revisions to the TSCA section 4(e) *Priority Testing List* at this time.

DATES: Comments must be received on or before September 3, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0206, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2009–0206. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2009–0206. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This notice is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process TSCA-covered chemicals and you may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this notice is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-DOM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Toxic Substances Control Act (TSCA) (15 U.S.C. 260l *et seq.*) authorizes the Administrator of EPA to promulgate regulations under TSCA section 4(a) requiring testing of chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the ITC to recommend chemicals and chemical groups to the Administrator of EPA for priority testing consideration. Section 4(e) of TSCA directs the ITC to revise the TSCA section 4(e) *Priority Testing List* at least every 6 months.

You may access additional information about the ITC at *http://www.epa.gov/opptintr/itc*.

A. The 64th ITC Report

The ITC has no revisions to the TSCA section 4(e) *Priority Testing List* at this time.

B. Status of the Priority Testing List

The *Priority Testing List* includes 2 alkylphenols, 12 lead compounds, 16 chemicals with insufficient dermal absorption rate data, and 207 HPV Challenge Program orphan chemicals.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: July 27, 2009.

Wendy C. Hamnett,

Acting Director, Office of Pollution Prevention and Toxics.

Sixty-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency

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Summary

The ITC has no revisions to the Toxic Substances Control Act (TSCA) section 4(e) *Priority Testing List* at this time.

The TSCA section 4(e) *Priority Testing List* is Table 1 of this unit.

TABLE 1.—TSCA SECTION 4(E) PRIORITY TESTING LIST (MAY 2009)

ITC Report	Date	Chemical Name/Group	Action
31	January 1993	2 Chemicals with insufficient dermal absorption rate data	Designated
32	May 1993	10 Chemicals with insufficient dermal absorption rate data	Designated
35	November 1994	4 Chemicals with insufficient dermal absorption rate data	Designated
37	November 1995	Branched 4-nonylphenol (mixed isomers)	Recommended
41	November 1997	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	Recommended
55	December 2004	203 High Production Volume (HPV) Challenge Program orphan chemicals	Recommended
56	August 2005	4 HPV Challenge Program orphan chemicals	Recommended
60	May 2007	12 Lead and lead compounds	Recommended

I. Background

The ITC was established by section 4(e) of TSCA ''to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of rules for testing under section 4(a).... At least every six months ..., the Committee shall make such revisions to the *Priority Testing List* as it determines to be necessary and transmit them to the Administrator together with the Committee's reasons for the revisions'' (Public Law 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*). ITC reports are available from the ITC's website (*http://www.epa.gov/opptintr/itc*) within a few days of submission to the EPA Administrator and from the EPA's website (*http://www.epa.gov/fedrgstr*) after publication in the **Federal Register**. The ITC produces its revisions to the *Priority Testing List* with administrative and technical support from the ITC staff, ITC members, and their U.S. Government organizations, and contract support provided by EPA. ITC members and staff are listed at the end of this report.

II. ITC's Activities During this Reporting Period (November 2008 to May 2009)

During this reporting period, the ITC continued to discuss nanoscale materials and EPA's Nanoscale Materials Stewardship Program (NMSP) (For details on the NMSP, see the **Federal Register** issue of January 28, 2008 (73 FR 4861) (FRL–8344–5), available on-line at *http://www.epa.gov/fedrgstr*.) The ITC's initial discussions of nanoscale materials occurred in 2004 with briefings by scientists from EPA, National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH), and National Institute of Standards and Technology (NIST) and a review of the National Toxicology Program (NTP) Toxicological Evaluation of Nanoscale Materials. At that time, several ITC members were participating on an informal interagency nanoscale materials workgroup and were aware of the need to understand the health and environmental effects of nanoscale materials.

The EPA briefing discussed the potential regulation of nanoscale materials as new chemicals under TSCA section 5. The NIEHS briefing described the goal of the NTP research program, i.e., to evaluate the toxicological properties of major nanoscale materials classes and use these as model systems to investigate fundamental questions concerning if and how nanoscale materials can interact with biological systems. The NIOSH briefing focused on the impact of nanotechnology on occupational health. The briefing acknowledged that while the prevalence and types of nanoscale particles in the workplace were not yet determined, there were concerns that nanoscale particles could exhibit a high deposition fraction in the respiratory tract, appear to be toxic and inflammatory to the lung, and may migrate to systemic sites. The NIST contribution to the nanotechnology area is to develop needed measurements, data, and standards; develop infrastructure measurement capabilities; provide the metrology tools and techniques; and transfer measurement capabilities to the appropriate communities.

In 2006, the ITC reviewed EPA's nanotechnology white paper and received a briefing on EPA's nanotechnology research programs. Since then, the ITC has discussed the importance of nanotechnology, but questioned how nanotechnology chemicals for which there are very few Chemical Abstracts Service Registry (CAS) numbers should be discussed in ITC reports or added to the ITC's *Priority Testing List*.

In 2009, the ITC reviewed the EPA's interim report on the Nanoscale Materials Stewardship Program (*http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf*). EPA intends to develop a proposed TSCA section 8(a) rule to obtain information on the production, uses, and exposures of existing nanoscale materials. EPA has indicated that it will ensure that the chemicals where there is ITC interest as described in this unit are either included in that action or are otherwise new chemical substances subject to premanufacture notification (PMN) reporting under TSCA. EPA also intends to develop a proposed TSCA section 4 rule to develop needed environmental, health, and safety data. The ITC also noted NIOSH's guidelines, ''Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials,'' that are available at *http://www.cdc.gov/niosh/topics/nanotech/safenano*.

1. At this time, there are several U.S. Government organizations on the ITC that continue to have data needs for nanoscale materials. Many of these nanoscale materials do not have CAS numbers, or have CAS numbers that may be associated with the non-nanoscale chemical.

a. Occupational exposure data needs include:

i. Recent non-CBI estimates of annual production and/or importation volume data and trends, and use information, including percentages of production or importation that are associated with different uses.

ii. Estimates of the numbers of workers associated with production and downstream uses.

iii. Workplace area and/or personal breathing zone concentrations to which workers may be exposed during manufacturing, processing, and downstream use scenarios.

b. Mammalian toxicology data needs include:

i. Human health effects data such as case reports and epidemiological studies of workers.

ii. Acute, subchronic, chronic, pulmonary, reproductive, and developmental animal toxicity data as well as pharmacokinetics, genotoxicity, and carcinogenicity data.

c. Environmental data needs include:

i. Ecological effects data for aquatic and terrestrial organisms, birds, and wild mammals.

ii. Chemical fate data such as biodegradation, photolysis, hydrolysis, oxidation, and reduction.

iii. Physical or chemical property data such as melting and boiling points, partition coefficients as well as metrology data.

2. At this time, the U.S. Government organizations on the ITC have data needs for occupational exposure and mammalian toxicology data for the following nanoscale materials, and are reviewing data submitted in PMNs or in response to the NMSP:

a. Materials having CAS numbers that are only nanoscale at the molecular level:

- C_{60} fullerenes–CAS No. 135105–52–1 (this is the generic C_{60} fullerene; many other CAS numbers exist for specific C_{60} fullerene structural isomers, including, for example, CAS No. 99685–96–8, for [5,6]Fullerene-C_{60}-Ih)
- C_{90} fullerenes–CAS No. 135113–17–6 (this is the generic C_{90} fullerene; other CAS numbers exist for specific C_{90} fullerene structural isomers)

b. Materials having CAS numbers that can exist in the nanoscale and bulk forms:

- Carbon black, nano form–CAS No. 1333–86–4
- Titanium oxide (TiO_2) nanowires–CAS No. 13463–67–7
- Titanium oxide (TiO_2) nanoparticles—CAS No. 13463–67–7
- Zinc oxide (ZnO), nano form—CAS No. 1314–13–2
- Silver, nano form—CAS No. 7440–22–4
- Silica [crystalline], nano form—CAS No. 7631–86–9
- Quartz (SiO_2), nano form—CAS No. 14808–60–7
- Cerium oxide (CeO_2), nano form—CAS No. 1306–38–3
- Indium tin oxide, nano form—CAS No. 50926–11–9
- Indium tin oxide ($In_{1.69}Sn_{0.15}O_{2.85}$), nano form—CAS No. 71243–84–0
- Indium tin oxide ($In_{0.01}SnO_2$), nano form—CAS No. 212075–26–8
- Indium tin oxide ($In_{0.02}Sn_{0.98}O_{1.99}$), nano form—CAS No. 180090–96–4
- Dendrimers—there are a number of CAS numbers describing certain compositions of dendrimers

c. Materials with no CAS numbers that either can exist in both the nano and bulk forms or are only nanoscale:

- Single–walled carbon nanotubes
- Multi–walled carbon nanotubes
- Carbon nanofibers
- Quantum dots with Cd core
- Quantum dots with Se core
- Nanoceramic particles
- Nanoclays

III. The TSCA Interagency Testing Committee

Statutory Organizations and Their Representatives

Council on Environmental Quality
Vacant

Department of Commerce
National Institute of Standards and Technology
Dianne Poster, Alternate

National Oceanographic and Atmospheric Administration
Tony Pait, Member, Chair

Environmental Protection Agency
John Schaeffer, Member
Gerry Brown, Alternate

National Cancer Institute
Vacant

National Institute of Environmental Health Sciences
Scott Masten, Alternate

National Institute for Occupational Safety and Health
Gayle DeBord, Member
Dennis W. Lynch, Alternate

National Science Foundation
Margaret Cavanaugh, Alternate

Occupational Safety and Health Administration
Thomas Nerad, Member, Vice-Chair
Maureen Ruskin, Alternate

Liaison Organizations and Their Representatives

Agency for Toxic Substances and Disease Registry
Daphne Moffett, Member
Glenn D. Todd, Alternate

Consumer Product Safety Commission
Jacqueline Ferrante, Member

Department of Agriculture
Clifford P. Rice, Member
Laura L. McConnell, Alternate

Department of Defense
Laurie Roszell, Member

Department of the Interior
Barnett A. Rattner, Member

Food and Drug Administration
Kirk Arvidson, Member
Ronald F. Chanderbhan, Alternate

Technical Support Contractor
Syracuse Research Corporation

ITC Staff
John D. Walker, Director
Carol Savage, Administrative Assistant

TSCA Interagency Testing Committee (7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; e-mail address: *savage.carol@epa.gov*; url: *http://www.epa.gov/opptintr/itc*.

[FR Doc. E9–18469 Filed 8–3–09; 8:45 am]
BILLING CODE 6560–50–S