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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 770

[EPA-HQ-OPPT-2011-0380; FRL-9342-4]

RIN 2070-AJ44

Formaldehyde; Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Formaldehyde Standards for Composite Wood Products Act (Title VI of the Toxic Substances Control Act (TSCA)) establishes formaldehyde emission standards for hardwood plywood, particleboard, and medium-density fiberboard (composite wood products) and directs EPA to promulgate implementing regulations by January 1, 2013. Pursuant to the requirements of TSCA Title VI, EPA is proposing a framework for a TSCA Title VI Third-Party Certification Program for composite wood products. Under the framework, third-party certifiers (TPCs) would be accredited by EPA-recognized accreditation bodies (ABs) so that TPCs may certify composite wood product panel producers under TSCA Title VI. This proposed rule identifies the roles and responsibilities of the TPCs and ABs involved, as well as the criteria for participation in the TSCA Title VI Third-Party Certification Program. The Agency is proposing the TSCA Title VI Third-Party Certification Program framework prior to the rest of the TSCA Title VI implementing regulations in order to allow interested parties an opportunity to comment and to begin identifying the business practices and infrastructure that may need to be modified or developed in order to effectively participate in the

program.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0380, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online 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. ATTN: Docket ID Number EPA-HQ-OPPT-2011-0380.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2011-0380. 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-2011-0380. EPA's policy is that all comments received will be included in the docket without change and may be made available online 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](http://www.regulations.gov) or email. The [regulations.gov](http://www.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 email comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your email 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 legal 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: *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*.

For technical information contact: Erik Winchester, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6450; email address: *winchester.erik@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you certify domestic or international composite wood products. Potentially affected entities may include, but are not limited to:

- Reconstituted wood product manufacturing (NAICS code 321219).
- Engineering services (NAICS code 541330).
- Testing laboratories (NAICS code 541380).
- Administrative management and general management consulting services (NAICS code 541611).
- All other professional, scientific, and technical services (NAICS code 541990).
- All other support services (NAICS code 561990).
- Business associations (NAICS code 813910).

- Professional organizations (NAICS code 813920).

This list is not intended to be exhaustive, but rather provides a guide for readers likely to be affected by this action. To determine whether you, your business, or your agency is affected, you should carefully examine this proposed rule and the TSCA Title VI (Ref. 1). If you have any questions regarding the applicability of this action to a particular entity, consult the technical 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 email. 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 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

A. Executive Summary

1. *Purpose of the regulatory action.* EPA is proposing a framework for a TSCA Title VI Third-Party Certification Program for composite wood products. Under the framework, TPCs would be accredited by EPA-recognized ABs so that TPCs may certify composite wood product panel producers under TSCA Title VI, 15 U.S.C. 2697. TSCA Title VI gives EPA the authority to promulgate regulations relating to “third-party testing and certification” and “auditing and reporting of third-party certifiers” with regards to composite wood products. EPA believes that third-party certification is an essential component in ensuring compliance with the TSCA Title VI emission standards for composite wood products.

2. *Summary of the major provisions.* This proposal provides a framework for the

TSCA Title VI Third-Party Certification Program. It lists the qualifications for ABs that wish to participate in the program, the process for applying to participate in the program, and the responsibilities of participating ABs. It also lists the qualifications for TPCs that wish to become TSCA Title VI accredited, the process for applying to become TSCA Title VI accredited, and the responsibilities of TSCA Title VI accredited TPCs.

3. *Costs and impacts.* EPA has prepared an analysis of the potential costs and impacts associated with this rulemaking. This analysis is summarized in greater detail in Unit VI.A. The following chart provides a brief outline of the costs and impacts of this proposal:

Category	Description
Costs	The annualized costs of this proposed rule are estimated at approximately \$34,000 per year using either a 3% discount rate or a 7% discount rate.
Small Entity Impacts	This rule would impact an estimated 9 small entities, of which 8 are expected to have impacts of less than 1% of revenues or expenses, and 1 is expected to have impacts between 1% and 3%.
Effects on State, Local, and Tribal Governments	Government entities are not expected to be subject to the rule's requirements, which apply to third-party certifiers and accreditation bodies. The rule does not have a significant intergovernmental mandate, significant or unique effect on small governments, or have Federalism implications.

B. What Action is the Agency Taking?

Title VI of TSCA directs EPA to promulgate implementing regulations by January 1, 2013 (Ref. 1). EPA is issuing this proposed rule under TSCA Title VI to establish a framework for a TSCA Title VI Third-Party Certification Program whereby TPCs are accredited by ABs so that they may certify composite wood product panel producers under TSCA Title VI. This proposed rule identifies the roles and

responsibilities of the groups involved in the TPC process (EPA, ABs, and TPCs), as well as the criteria for participation in the program. This proposal contains general requirements for TPCs, such as conducting and verifying formaldehyde emission tests, inspecting and auditing panel producers, and ensuring that panel producers' quality assurance and quality control procedures comply with the regulations set forth in this proposed rule. In a subsequent document, EPA will propose additional requirements including the frequency of testing, means for showing test method equivalence, and other implementing provisions as required under TSCA Title VI, such as labeling, chain of custody requirements, sell-through provisions, recordkeeping, and enforcement.

C. What is the Agency's Authority for Taking this Action?

EPA is issuing this proposed rule pursuant to the Formaldehyde Standards for Composite Wood Products Act (Ref. 1), which provides authority for the Administrator to "promulgate regulations to implement the standards required under subsection (b) in a manner that ensures compliance with the emission standards described in subsection (b)(2)." This provision includes authority to promulgate regulations relating to "third-party testing and certification" and "auditing and reporting of third-party certifiers."

D. Formaldehyde Sources and Health Effects

Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor. It is found in resins used in the manufacture of composite wood products (e.g., hardwood plywood, particleboard, and medium-density fiberboard). It is also found in household products such as glues, permanent press fabrics, carpets, antiseptics, medicines, cosmetics, dishwashing liquids, fabric softeners, shoe care agents, lacquers, plastics, and paper product coatings. It is a by-product of combustion and certain other

natural processes. Examples of sources of formaldehyde gas inside homes include cigarette smoke, unvented, fuel-burning appliances (gas stoves, kerosene space heaters), and composite wood products made using formaldehyde-based resins (Ref. 2).

Formaldehyde is both an irritant and a known human carcinogen (Ref. 3). Depending on concentration, formaldehyde can cause eye, nose, and throat irritation, even when exposure is of relatively short duration. In the indoor environment, sensory reactions and various symptoms resulting from mucous membrane irritation are potential effects. There is also evidence that formaldehyde may be associated with changes in pulmonary function and increased risk of asthma in children (Ref. 2).

The Integrated Risk Information System (IRIS) Program of EPA's Office of Research and Development (ORD) recently completed a draft assessment of the potential cancer and non-cancer health effects that may result from chronic inhalation exposure to formaldehyde (Ref. 4). This draft IRIS assessment was peer reviewed by the National Academy of Sciences (NAS) (Ref. 5). EPA is currently considering the peer review comments. Both the National Toxicology Program (Ref. 3) and the International Agency for Research on Cancer (Ref. 6) have concluded that formaldehyde is a known human carcinogen. However, in revising the draft IRIS assessment, EPA is following the 2011 recommendation of the National Research Council to evaluate the weight of evidence for specific cancer types in multiple organs, including specific respiratory tract sites and specific lymphohematopoietic cancer subtypes. This analysis will be used to derive a unit risk estimate in the revised draft that reflects more recent data and an updated review of the cancer hazard in humans and animals.

E. History of this Action

1. *Legislative history.* On July 7, 2010, President Obama signed into law the Formaldehyde Standards for Composite Wood Products Act (Ref. 1). This legislation adds Title VI to TSCA and establishes formaldehyde emission standards for hardwood plywood, particleboard, and medium-density fiberboard. These emission standards are identical to the California Air Resources Board's (CARB) Airborne Toxic Control Measure (ATCM) Phase II standards (Ref. 7). Title VI of TSCA directs EPA to promulgate implementing regulations by January 1, 2013, that address: Labeling, chain of custody requirements, sell-through provisions, ultra low-emitting formaldehyde (ULEF) resins, no-added formaldehyde-based (NAF) resins, finished goods, third-party testing and certification, auditing and reporting of third-party certifiers, recordkeeping, enforcement, laminated products, and products containing *de minimis* amounts of composite wood.

This proposed rule establishes a framework for a TSCA Title VI Third-Party Certification Program to help ensure that regulated composite wood products consistently meet the TSCA Title VI formaldehyde emission standards. EPA will issue a separate proposed rule at a later date that includes the rest of the TSCA Title VI implementing regulations. That separate proposed rule will include specific testing responsibilities of TPCs.

2. *The CARB ATCM.* The CARB ATCM establishes emission standards for composite wood products sold, offered for sale, supplied, used, or manufactured for sale in California (Ref. 7). It includes requirements for manufacturers of composite wood products, distributors, importers, fabricators, retailers, and TPCs with provisions on sell-

through dates, labeling, recordkeeping, testing, and certification. It also includes special provisions for manufacturers of composite wood products with ULEF and NAF resins.

Under the CARB ATCM, manufacturers of composite wood products must have their compliance with the emission standards certified by a TPC approved by CARB (Ref. 8). The CARB ATCM defines a third-party certifier as “an organization or entity approved by the Executive Officer that: (A) verifies the accuracy of the emission test procedures and facilities used by manufacturers to conduct formaldehyde emission tests, (B) monitors manufacturer quality assurance and quality control programs, and (C) provides independent audits and inspections.” In order to become a CARB approved TPC, prospective certifiers must submit an application to the CARB Executive Officer containing:

- a. Evidence of actual field experience in the verification of laboratories and wood products, to demonstrate how the applicant will be able to competently perform the TPC requirements under the CARB ATCM.

- b. Evidence of the ability to properly train and supervise inspectors.

- c. Evidence of a current “product accreditation body” accreditation issued by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

- d. A list of the composite wood products that the applicant is applying to verify and evidence that the applicant is qualified to verify these products (Ref. 9).

If the TPC’s application is approved, the CARB Executive Officer issues a CARB Executive Order with a duration of 2 years. Upon the expiration date of the CARB Executive Order, a TPC may apply for re-accreditation by submitting an updated

application. The CARB Executive Officer may, “for good cause,” modify or revoke a CARB Executive Order approving a TPC after giving the TPC the opportunity for a hearing.

Under the CARB ATCM, CARB approved TPCs are required to verify that composite wood product manufacturers are complying with the quality assurance and quality control requirements, verify formaldehyde emission test results, work with manufacturers to establish quality control limits for each product type and production line, provide independent inspections and audits of manufacturers and records, use laboratories that are certified by an AB that is a signatory to the ILAC MRA, maintain records for 2 years; and provide an annual report to CARB. CARB maintains a list of approved TPCs on its website (Ref. 8). The annual report must include:

- A list of manufacturers certified by the TPC during the previous calendar year, including the resins used by the manufacturers and the average and range of formaldehyde emissions.
- A list of any non-complying events by manufacturers.
- Certified laboratories and primary or secondary test methods utilized by the TPC.
- Results of inter-laboratory testing comparisons for laboratories used by the TPC.

3. *Recent activities related to this proposed rule.* On March 24, 2008, 25 organizations and approximately 5,000 individuals petitioned EPA under section 21 of TSCA to use its authority under section 6 of TSCA to adopt the CARB ATCM nationally (Ref. 10). The petitioners asked EPA to assess and reduce the risks posed by formaldehyde emitted from hardwood plywood, particleboard, and medium-density

fiberboard by exercising its authority under TSCA section 6 to adopt and apply nationwide the CARB formaldehyde emissions regulation for these composite wood products. In addition, petitioners requested EPA to extend this regulation to include composite wood products used in manufactured homes. The petitioners expressed particular concern over the levels of formaldehyde found in emergency housing provided for persons displaced from their homes by Hurricane Katrina and noted that there are no Federal regulations on formaldehyde emissions from composite wood products other than the Department of Housing and Urban Development's (HUD) regulations for manufactured housing at 24 CFR 3280.308.

On June 27, 2008, EPA issued a notice explaining the Agency's decision to grant in part and deny in part the petitioners' request (Ref. 11). EPA denied the petitioners' request to immediately pursue a TSCA section 6 rulemaking, stating that the available information at the time was insufficient to support an evaluation of whether formaldehyde emitted from hardwood plywood, particleboard, and medium-density fiberboard presents or will present an unreasonable risk to human health (including cancer and non-cancer endpoints) under TSCA section 6. As discussed in detail in the **Federal Register** notice announcing EPA's response to the petition, EPA's evaluation of the data provided by the petitioners revealed significant information gaps that would have needed to be filled to support an evaluation of whether use of formaldehyde in these products presents or will present an unreasonable risk under TSCA section 6. However, EPA did agree to initiate a proceeding to investigate whether and what type of regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from pressed wood products.

Accordingly, on December 3, 2008, EPA issued an Advance Notice of Proposed Rulemaking (ANPR) that announced EPA's intention to investigate whether and what regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from the products covered by the CARB ATCM as well as other pressed wood products (Ref 12). To help inform EPA's decision on the best ways to address risks posed by formaldehyde emissions from pressed wood products, the Agency requested public comments and held six half-day public meetings in Research Triangle Park, NC; Portland, OR; Chicago, IL; Dallas, TX; Washington, DC; and New Orleans, LA. EPA received and reviewed comments submitted during the ANPR comment period which can be found at [regulations.gov](https://www.regulations.gov) under docket number EPA-HQ-OPPT-2008-0627.

F. Objectives of the Framework for the Third-Party Certification Program

EPA believes that the TSCA Title VI Third-Party Certification Program must be impartial and applicable uniformly to composite wood products "sold, supplied, offered for sale, or manufactured in the United States" regardless of origin, whether domestic or international. TSCA section 601(b)(1). This proposed rule aims to ensure that these objectives are met, along with ensuring the consistent application of the TPC requirements of TSCA Title VI, by requiring the use of voluntary consensus standards for the TSCA Title VI Third-Party Certification Program, and by leveraging the expertise of international ABs. Additionally, this proposed rule is intended to be as consistent as practicable with the TPC requirements under the CARB ATCM. By aligning itself with the existing CARB ATCM requirements, EPA seeks to avoid differing or duplicative regulatory requirements that would result in an increased burden on the regulated

community.

Qualified and experienced TPCs are essential to ensuring that domestic and foreign panel producers supplying products to the United States have quality assurance and quality control procedures, are having their products tested to determine that they are compliant with formaldehyde emissions standards, and are otherwise acting in manner that is consistent with the requirements of TSCA Title VI. The TSCA Title VI formaldehyde emissions standards apply to hardwood plywood, particleboard, and medium-density fiberboard sold, supplied, offered for sale, or manufactured (including imported) in the United States. Because TSCA defines “manufacture” to include “import into the customs territory of the United States” the standards are applicable regardless of whether the composite wood product is manufactured domestically or imported from abroad.

There are a substantial number of panel producers and TPCs that operate solely outside of the United States. Currently, 27 of the 36 CARB-approved TPCs are based outside the United States (Ref.8). To ensure that oversight of TPCs is as strong abroad as it is domestically, EPA believes a TSCA Title VI Third-Party Certification Program framework should include internationally operating ABs to overcome potential logistical limitations that may hinder regular and rigorous inspection of TPCs operating outside the United States. Many ABs have a global reach, preexisting infrastructure, and experience working in foreign countries, which EPA believes makes them ideal for evaluating the qualifications of TPC candidates. Under EPA’s proposed TSCA Title VI Third-Party Certification Program framework, ABs would review, accredit, oversee, audit, and inspect both domestic and foreign TPCs--activities that would enable EPA to ensure the

legitimacy of both TPCs and panel producers in the United States and abroad. The ABs' oversight and auditing functions verify that TPCs are fulfilling their regulatory obligations uniformly across the global marketplace. EPA would retain its statutorily delegated roles in program design, establishing the standards, enforcement, and oversight; and utilize ABs to strengthen performance of TPCs.

G. What Background Information was Used to Develop the Framework for a Third-Party Certification Program?

Effective and successful implementation of EPA's TSCA Title VI Third-Party Certification Program requires that panel producers have in place formaldehyde emissions testing programs and quality assurance and quality control programs for product manufacturing. To achieve these outcomes, EPA is proposing to require the use of voluntary consensus standards for those participating as a TPC in the TSCA Title VI Third-Party Certification Program. In developing this proposed rule, EPA reviewed established voluntary consensus standards that are relied on by industries around the world as a means of ensuring the competency of third-parties in particular fields of technical activity such as testing, instrument calibration, and product performance certification. In addition to reviewing existing voluntary consensus standards, EPA reviewed other successful third-party certification programs that use voluntary consensus standards to determine if such programs could be used as models for the TSCA Title VI Third-Party Certification Program.

Third-party certification involves a process by which a product, process, or service is reviewed by a reputable and qualified independent third-party to verify that a set of norms, criteria, claims, practices, or standards are being met. Third-party certification has been widely and successfully used for decades by a number of industries

such as engineering, electronics, energy, software, automotive, and food and consumer products. The standards used in third-party certification are typically voluntary consensus standards developed by nationally or internationally recognized standards-producing organizations or industry groups. Voluntary consensus standards establish uniform engineering or technical criteria, methods, processes, and practices for an industry practice or product, and are developed by experts in the relevant field through a process that allows input by all persons interested and affected by the scope or provisions of the standard. Parties in that industry then choose to accept and voluntarily abide by the consensus standards. Otherwise, the existence of multiple and non-harmonized standards for similar products, processes, and services in different countries or regions can create barriers to trade.

1. *Voluntary consensus standards.* In order for EPA to ensure that the Third-Party Certification Program under TSCA Title VI is effective in ensuring compliance with the emission standards, impartial in its operations, and applicable both domestically and internationally, the Agency proposes requiring the use of voluntary consensus standards as the basis for operating the TSCA Title VI Third-Party Certification Program. EPA specifically proposes using International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) voluntary consensus standards and guides as general requirements for third-party certifications. In addition to industry experts, international organizations--both governmental and non-governmental--work in cooperation with ISO and IEC to develop their consensus standards. In the field of conformity assessment, the ISO Committee on Conformity Assessment (CASCO) is responsible for the development of international standards and guides.

The appropriate ISO/IEC standards and guide that EPA proposes requiring are:

- ISO/IEC Guide 65:1996(E), General Requirements for Bodies Operating Product Certification Systems. This is the international voluntary consensus standard that specifies general requirements for a third-party operating a product certification program (Ref. 13). These general requirements would help ensure that the TPC is competent and reliable in certifying compliant composite wood products.

- ISO/IEC 17011:2004(E), Conformity Assessments--General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. This international voluntary consensus standard offers the general requirements for ABs assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirement document for the peer evaluation process for mutual recognition arrangements between ABs (Ref. 14). These general requirements would help ensure that the ABs are competent and reliable in accrediting TPCs.

- ISO/IEC 17025:2005(E), General Requirements for the Competence of Testing and Calibration Laboratories. This international voluntary consensus standard specifies the general requirements for competence in carrying out tests and/or calibrations, including sampling (Ref. 15). EPA believes that requiring TPCs to use laboratories that follow these requirements would help ensure that reliable and accurate test results are obtained.

- ISO/IEC 17020:1998(E), General Criteria for the Operation of Various Types of Bodies Performing Inspections. This international voluntary consensus standard specifies general criteria for the competence of impartial bodies performing inspection. It is intended for use by inspection bodies and their accreditation bodies (Ref. 16).

EPA believes that requiring TPCs to follow these requirements would help ensure greater homogeneity of the inspection process among the TPCs recognized by EPA.

The appropriate use of each guide and standard and a description of the party responsible under the proposed TPC framework for ensuring compliance with the standard are detailed in Unit III. The use of the guide and standards furthers the goal of the National Technology Transfer and Advancement Act (NTTAA), as discussed in Unit VI. These ISO standards and guide will be made available for viewing in the EPA/DC Public Reading Room and, during the public comment period. Online access to the ISO standards will also be available to the public free of charge during the comment period through the ANSI website at <http://webstore.ansi.org/EPA/Download.aspx>. A user account, which may be created through the ANSI website, is required to access the standards.

2. International accreditation and inspection oversight organizations. In the profession of conformity assessment (i.e., the process of ensuring an organization responsible for implementing a consensus standard does so in conformance with the standard) oversight of conformity assessment bodies, such as TPCs, is done by organizations known as ABs. An AB provides an impartial verification of the competency of conformity assessment bodies such as TPCs. The ABs themselves also have oversight typically performed by an association or cooperative of conformity experts and other ABs through a peer evaluation process. Because the proposed TPC framework is international in scope and will employ the use of internationally accepted consensus standards, EPA reviewed the structure and functions of well known international organizations that were established decades ago to specifically provide

oversight of ABs.

The two international AB oversight bodies that EPA examined for this proposed rule are the International Accreditation Forum, Inc. (IAF) and ILAC. EPA believes that using a system where an AB's qualifications are verified by international oversight bodies such as these and in which the ABs in turn assess the conformity of TPCs to international voluntary consensus standards would ensure that the requirements of TSCA Title VI are met. The specific details of how EPA proposes to leverage this system to ensure compliance with the TSCA Title VI are detailed in Unit III.

The IAF is an association of conformity assessment bodies and other bodies. IAF requires its member ABs to comply with appropriate international conformity assessment standards. The IAF Multilateral Recognition Arrangement (MLA) is an agreement between AB members of the IAF whereby the ABs conduct regular evaluations of each other to assure the equivalence of their accreditation programs. This MLA agreement allows companies with an accredited conformity assessment certification in one part of the world to have that certification recognized everywhere else in the world, thereby facilitating international trade (Ref. 17). The MLA certification provides documentation that a person or an organization has been accredited to a specific standard or scheme by an IAF MLA signatory AB. In addition, IAF through its MLA ensures that all ABs who are capable of accrediting product certification bodies, such as TPCs, are in conformance with ISO/IEC Guide 65:1996(E). By requiring a TPC to be accredited to ISO/IEC Guide 65:1996(E) by a qualified AB that has an IAF endorsement through level 3 of the IAF Scope, or is a member of an equivalent oversight body, EPA believes that the TPC will be in conformance with ISO/IEC Guide 65:1996(E), the voluntary consensus standard

used to ensure proper product certification. Level 3 of the IAF Scope is the level of accreditation which needs to be accomplished by a Product AB under that program to ensure that the Product AB is qualified to accredit the TPC.

The ILAC is an international cooperation of laboratory and inspection ABs formed to help remove technical barriers to trade. ABs around the world, which have been evaluated by peers as competent, have signed an MRA that enhances the acceptance of products and services across national borders (Ref. 18). By requiring a TPC's emissions testing laboratory, or its contract laboratory, to be accredited by an AB that is a signatory to the ILAC MRA or equivalent oversight body, EPA believes that there will be a greater assurance of compliance with ISO/IEC 17025:2005(E), the voluntary consensus standard that is critical to ensuring adequate verification of performance for TSCA Title VI required laboratory formaldehyde emissions testing.

3. Other third-party certification programs that were evaluated. As mentioned in Unit II.F., EPA aims to develop a TSCA Title VI Third-Party Certification Program that incorporates lessons learned from other third-party certification programs. In addition, EPA is particularly interested in harmonizing, to the extent practicable, with the CARB's third-party certification program to avoid differing or duplicative regulatory requirements.

In developing the TSCA Title VI Third-Party Certification Program framework as presented in this proposed rule, EPA started with a review of CARB's program, as described in Unit II.E. This included meeting with CARB, the composite wood industry, and CARB-approved TPCs.

EPA also reviewed other EPA and Federal programs that have elements relevant

to EPA's goals for this proposed program, such as the use of voluntary consensus standards and/or a third-party product certification process. The following EPA and Federal programs were reviewed during development of the proposed TSCA Title VI Third-Party Certification Program framework:

a. *National Lead Laboratory Accreditation Program*. EPA established the National Lead Laboratory Accreditation Program (NLLAP) in 1992, to provide protocols, criteria, and minimum performance standards for analysis of lead in paint, dust, and soil, as required under TSCA section 405 (Ref. 19). Section 405 of TSCA further directs EPA, in consultation with the Department of Health and Human Services (HHS), to develop a program to certify qualified lead testing laboratories. The NLLAP provides the public with a list of qualified laboratories that have met EPA criteria and demonstrated the capability to accurately analyze paint chip, dust, and soil samples for lead. EPA ensures that laboratories comply with these EPA criteria by having them evaluated and accredited by third-party laboratory ABs according to ISO/IEC performance consensus standards. In order to assure the public that a Laboratory AB is capable of performing an adequate assessment of participating laboratories, EPA enters into a recognition agreement with the AB in recognition of its capability to perform adequate laboratory assessments.

For a laboratory to qualify for recognition under the NLLAP, it must pass on-site audits conducted by one of the four laboratory ABs with which EPA has a recognition agreement. The Laboratory ABs recognize NLLAP laboratories in conformance with ISO/IEC 17025:2005(E). Laboratories recognized under the NLLAP must also successfully perform, on a continuing basis, in the Environmental Lead Proficiency Analytical Testing (ELPAT) Program. The ELPAT is a proficiency testing program that

is designed to evaluate the analytical performance of laboratories by providing the laboratory with standardized test samples on a quarterly basis and evaluating their results against consensus results from a set of reference laboratories.

The NLLAP has successfully demonstrated over the years that EPA recognized laboratories are capable of accurately analyzing for lead in paint chips, dust wipes, and soil samples. Therefore, EPA believes that the third-party processes employed by the NLLAP, which include the use of third-party laboratory ABs that accredit laboratories by using voluntary consensus standards, along with additional specified laboratory testing protocols, demonstrate that a similar third-party certification program can be used successfully under TSCA Title VI.

b. National Voluntary Conformity Assessment System Evaluation Program.

Another program that EPA reviewed is the National Voluntary Conformity Assessment System Evaluation (NVCASE) Program at the Department of Commerce's National Institute of Standards and Technology (NIST). NIST, through its Standards Services Division, offers this voluntary program to evaluate and recognize organizations which support third-party conformity assessment activities. The NVCASE Program includes activities related to third-party laboratory testing, third-party product certification, and quality system registration. After an NVCASE Program evaluation, NIST provides recognition to qualified U.S. organizations that effectively demonstrate conformance with established criteria. The ultimate goal is to help U.S. manufacturers satisfy applicable product requirements mandated by foreign or U.S. regulatory authorities through conformity assessment procedures. Under the NVCASE Program, NIST accepts requests from only domestic TPCs for domestic and international accreditation. The use of NIST's

NVCASE Program in the United States would significantly hamper the ability of foreign TPC candidates to receive and maintain accreditation and would not allow EPA to meet its goal of providing testing and certification and auditing and reporting of all TPCs, domestic as well as international.

c. *Other EPA programs.* EPA also considered the product certification components of EPA's WaterSense and Energy Star programs. WaterSense is an EPA-sponsored partnership program launched in 2006 that seeks to protect the future of our nation's water supply by promoting water efficiency and enhancing the market for water-efficient products, programs, and practices. WaterSense helps consumers identify products and programs that meet WaterSense water efficiency and performance criteria. Energy Star is a joint program of the EPA and the Department of Energy (DOE) designed to help the consumers save money and protect the environment through the use of energy efficient products and practices. In 1992, EPA introduced Energy Star as a voluntary labeling program designed to identify and promote energy-efficient products to reduce greenhouse gas emissions.

Both the WaterSense and Energy Star certification programs specify the minimum criteria that EPA licensed product ABs must observe when certifying product conformance to specifications and when authorizing the use of the program's labels. These programs provide specific criteria for the application of ISO/IEC Guide 65:1996(E) in order to satisfy the criteria for certification of Energy Star and WaterSense products. They also provide the basis for consistent application of voluntary consensus standards by licensed ABs. The ISO/IEC Guide 65:1996(E) has been successfully used in these two programs for auditing, certifying, and reporting of the status of certification.

The Energy Star and WaterSense programs' use of ABs who certify under voluntary consensus standards for product certification also demonstrates the utility and workability of this approach.

Each of the aforementioned programs informed EPA's decision on how to develop an appropriate and credible third-party certification program for TSCA Title VI. EPA is proposing a framework under TSCA Title VI that incorporates elements of the CARB third-party certification program, the use of recognition agreements with ABs (e.g., as in NLAAP), and a product certification system element such as those used in the WaterSense and Energy Star programs.

III. What Does this Proposed Rule Do?

Illustration 1: TSCA Title VI Proposed Third-Party Certification Framework

International Standards Organizations

Develop consensus-based international standards for quality management and conformity assessment

International Standards Bodies

Ensure competency of Accreditation Bodies and their conformance with international standards

- Ensures AB conformance to ISO/IEC 17011¹
- Ensure ABs are qualified to oversee TPC conformance to ISO/IEC Guide 65 ISO/IEC17020 and/or ISO/IEC 17025

Accreditation Bodies

Ensure competency of TPCs; verify accuracy of emission test procedures, monitor TPC quality assurance programs, audit and inspect TPCs.

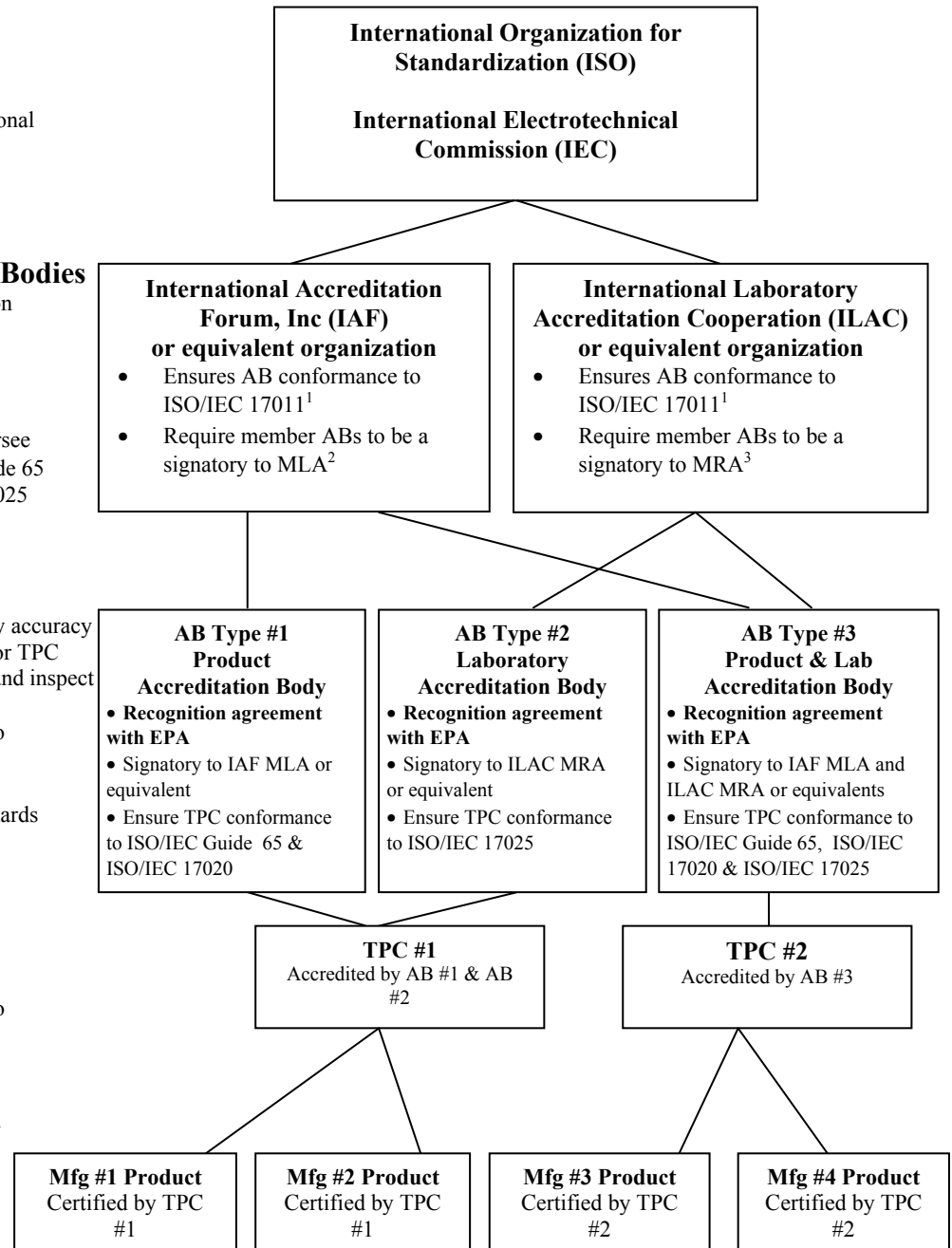
- Management systems conform to ISO/IEC 17011
- Ensure TPC conformance to applicable ISO/IEC Guide & Standards

Third-Party Certifiers

Ensure that panel producers are in compliance with statutory formaldehyde emission standards

- Management systems conform to ISO/IEC Guide 65
- Conform to applicable ISO/IEC Guide & Standards for Product & Laboratory Certification and Inspections

Composite Wood Panel Producers



¹ ISO/IEC 17011:2004(E) – Conformity Assessments--General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

² MLA – IAF’s Multilateral Recognition Arrangement requires AB signatories to demonstrate they are capable of accrediting product certification bodies in conformance with ISO/IEC Guide 65:1996(E) – General Requirements for Bodies Operating Product Certification Systems and ISO/IEC 17020:1998(E) – General Criteria for the Operation of Various Types of Bodies Performing Inspections.

³ MRA – ILAC’s Mutual Recognition Arrangement requires AB signatories to demonstrate they are capable of accrediting testing laboratories in conformance with ISO/IEC 17025:2005(E) – General Requirements for the Competence of Testing and Calibration Laboratories.

EPA is proposing a framework which it believes would enable implementation of a credible third-party certification program that ensures that TPCs are impartial and operate at the highest standards of competence. Although EPA's proposed TSCA Title VI Third-Party Certification Program framework, including the underlying requirements and implementation process, are based on, or are the same as, CARB's third-party certification program, EPA is proposing to also use qualified, internationally recognized ABs in implementing the program to establish a globally uniform process. Under EPA's proposed TSCA Title VI Third-Party Certification Program framework, ABs, recognized by EPA through recognition agreements, would accredit TPCs based on the requirements for TPCs established by EPA through this proposed rule. Like CARB, EPA would require that TPCs provide evidence of competency in four key areas:

- Experience and ability to verify the accuracy of formaldehyde emission testing of composite wood products.
- Experience in the composite wood product industry.
- Ability to monitor panel producer quality assurance programs for composite wood products.
- Ability to conduct auditing and inspection of panel producer activities and products.

However, unlike the CARB system, under which CARB evaluates and accredits TPCs without the input of ABs, ABs would conduct the evaluation and determine if the TPCs are competent in these four areas. Based on the results of ABs' evaluations that would be conducted according to EPA's requirements, including the standards for ABs in ISO/IEC Guide 65:1996(E) (which includes inspection accreditation based on compliance with

ISO/IEC 17020:1998(E)) and laboratory accreditation based on compliance with ISO/IEC 17025:2005(E), the ABs would accredit TPCs that meet the requirements. The ABs would also be required to participate in oversight activities, including recordkeeping, reporting to EPA, and auditing of TSCA Title VI accredited TPCs and their formaldehyde emissions testing laboratories. EPA would exercise authority to conduct independent oversight and actions, including the authority to review the determinations of ABs, and approve or revoke a TPC's TSCA Title VI accreditations based on the criteria laid out in this proposed rule.

While the AB component of EPA's proposed TSCA Title VI Third-Party Certification Program framework differs from the CARB program, EPA believes it will enhance the implementation of TSCA Title VI. The proposed TSCA Title VI Third-Party Certification Program framework is otherwise generally consistent with CARB's current third-party certification program requirements. Furthermore, EPA will work with CARB to help promote compatibility and consistency within the programs and to harmonize the third-party certification programs wherever practicable. EPA believes that compliance with the proposed the TSCA Title VI Third-Party Certification Program would not require substantial changes to procedures TPCs, laboratories, and panel producers currently use to conduct their TPC activities under the CARB ATCM (Ref. 7).

A. Requirements for Accreditation Bodies

Based on EPA's understanding of how the international consensus standards oversight industry is structured, EPA envisions that two types of ABs could be involved in implementation of the proposed TPC framework. The first type of AB is the "Product AB." The Product AB would be responsible for accrediting the TPCs, recordkeeping and

ensuring that a TPC is in conformance with ISO/IEC Guide 65:1996(E) (involving product certification systems) and ISO/IEC 17020:1998(E) (involving general criteria for inspections). The second type of AB is the “Laboratory AB.” The Laboratory AB would be responsible for ensuring that the TPC’s formaldehyde emissions testing laboratory (or its contracted laboratory) is of the highest quality and is in conformance with ISO/IEC 17025:2005(E) (involving the general requirements for laboratories conducting testing and/or calibrations, including sampling and calibration). EPA recognizes it is also possible that a single AB may have the ability to accredit both product certification and emissions testing, and therefore can accredit conformance to ISO/IEC Guide 65:1996(E), ISO/IEC 17020:1998(E), and ISO/IEC 17025:2005(E). In such cases, a single AB would be considered qualified to accredit TPCs for their product certification capabilities and also accredit the TPC laboratories for conducting formaldehyde emissions testing, and only that AB would need to be involved in accepting and reviewing TPC applications and implementing the ABs’ roles under the proposed TSCA Title VI Third-Party Certification Program framework.

1. Necessary qualifications of ABs to be candidates for participation in the EPA’s Title VI Third-Party Certification Program --a. Necessary qualifications of Product ABs.

To ensure that Product ABs are qualified to accredit TPC’s for conformance with ISO/IEC Guide 65:1996(E) and ISO/IEC 17020:1998(E), the Product AB would have to be a signatory to the IAF MLA, or a member of an equivalent oversight body. AB members of IAF are admitted to the IAF MLA only after a highly stringent evaluation of their operations by an IAF peer evaluation team which is charged with ensuring that the applicant member complies fully with both the international standards and IAF

requirements. Additionally, once an AB is a signatory to the IAF MLA, it is required to recognize the certificates issued by conformity assessment bodies accredited by all other signatories of the IAF MLA, with the appropriate scope (i.e., levels 1 through 3). The IAF MLA structure has 5 levels, and EPA would require the Product AB to be endorsed by IAF through level 3. Level 1 endorsement ensures that an AB is in conformity with ISO/IEC 17011:2004(E) and maintains that conformity; level 2 endorsement ensures that the AB has demonstrated basic competence to perform accreditation activities for product certification according to ISO/IEC Guide 65:1996(E) and ISO/IEC 17020:1998(E); and level 3 ensures that the AB has policies and procedures in place in their operations and management plans to accredit a TPC for product certification in conformance with ISO/IEC Guide 65:1996(E). In order to participate in the TSCA Title VI Third-Party Certification Program, a Product AB would have to provide EPA with documentation verifying its IAF endorsement that states the level of accreditation the AB received from IAF, or with confirmation that the AB is a member of an equivalent organization with an equivalent scope.

b. *Necessary qualifications of Laboratory ABs.* To ensure that the Laboratory ABs are qualified to accredit TPC laboratories, the proposed TPC framework would require that the Laboratory AB is a signatory to the ILAC MRA, or a member of an equivalent organization. To be a signatory to the ILAC MRA, an AB must pass an intensive evaluation carried out by peers and in accordance with the relevant rules and procedures contained in several ILAC publications. Once a signatory to the ILAC MRA, each Laboratory AB agrees to abide by its terms and conditions, and according to the ILAC evaluation procedures shall:

i. Maintain conformance with the ISO/IEC 17011:2004(E), related ILAC guidance documents, and any ILAC supplementary requirements.

ii. Ensure that all laboratories that they accredit comply with ISO/IEC 17025:2005(E) and related ILAC policy and guidance documents.

Under the proposed TPC framework, a TPC would be required to work with its Laboratory AB to provide the Product AB with documentation verifying the Laboratory AB's endorsement and scope of accreditation from ILAC, or documentation of membership in an equivalent organization.

EPA understands that not all ABs are signatories to either IAF or ILAC. EPA requests comment on what other oversight bodies or other organizations are equivalent to IAF and ILAC. An equivalent organization would provide a process of review and evaluation with a level of scrutiny and assessment of an AB's capabilities to ensure that an AB is qualified to accredited organizations based on the relevant ISO/IEC standards and guide.

2. Recognition agreement process and relationship between EPA and ABs. Under this proposed rule, the Product ABs and Laboratory ABs that are interested in participating in the TSCA Title VI Third-Party Certification Program would be required to submit an application to EPA to be formally recognized by EPA. Once EPA has reviewed the AB's credentials and deemed that the AB is qualified, EPA proposes to enter into a recognition agreement with Product and Laboratory ABs that want to offer services to accredit TPCs according to EPA's requirements. The recognition agreement would serve as a mechanism for EPA to formally recognize either a Product AB or a Laboratory AB (or both) as qualified to implement their respective roles under the TSCA

Title VI program. The recognition agreement with the Product AB would designate it as the recipient of applications from candidate TPCs that want to participate in the TSCA Title VI Third-Party Certification Program. As discussed in Unit II.G.3., similar recognition agreement approaches have been successfully used in a number of EPA programs. The recognition agreement is a signed agreement between EPA and each Product AB or Laboratory AB that would state:

- a. The regulatory requirements that have been and must continue to be met to be an EPA recognized AB.

- b. The roles and responsibilities of the AB under the TSCA Title VI Third-Party Certification Program.

- c. EPA's role and interactions with the AB during implementation of the TSCA Title VI Third-Party Certification Program.

- d. Criteria and processes for revoking the recognition agreement if either the Product AB or Laboratory AB fails to adhere to the conditions of the regulations.

All of the requirements and actions stated in the recognition agreement between EPA and each type of AB would be derived from the final rule requirements. If the AB applying to EPA for recognition is qualified to perform as both a Product AB and a Laboratory AB, then that AB would include both sets of credentials in its application package and would be recognized by EPA in the recognition agreement as performing both accreditation roles. The recognition agreement would be effective for 3 years, provided the AB continues to meet all of the regulatory requirements. After 3 years, the recognition agreement would be eligible for renewal.

In order to facilitate communication between EPA and ABs, EPA is proposing to

require ABs to designate an agent in United States in their applications. Any information provided by an AB or EPA to the designated agent would be equivalent to providing that information directly to the AB. The designated agent could not be a mailbox, answering machine, or other service where the agent is not physically present. The agent would need to be capable of accepting service of notices and processes made in administrative and judicial proceedings. EPA believes requiring a designated agent in the United States would help ensure compliance with the formaldehyde emission standards by facilitating the ability to enforce TSCA Title VI and its implementing regulations, which in turn encourages the regulated entities to fulfill their obligations under the statute and regulations. EPA requests comment on this proposed requirement.

EPA would designate an EPA Recognition Agreement Implementation Officer as a point of contact for ABs to consult with on implementation of the recognition agreement. EPA would be responsible for directly notifying participating ABs of changes in the TSCA Title VI Third-Party Certification Program. EPA would maintain a public list of all ABs with which EPA has a recognition agreement. The list would be posted on EPA's website and regularly updated.

3. *Proposed requirements once an AB is recognized.* Once EPA has entered into a recognition agreement with an AB, that AB becomes "recognized" by EPA as a Product AB, Laboratory AB, or both.

a. *Responsibilities of Product ABs in the TPC application process.* The Product AB's key TSCA Title VI TPC application review responsibilities would include:

i. Receiving and acting on TPC applications for their participation in the TSCA Title VI Third-Party Certification Program and thereby ensuring that the TPC is

accredited to ISO/IEC Guide 65:1996(E) and ISO/IEC 17020:1998(E).

ii. Transmitting copies of TPC applications and supporting documentation requested in the application based on the TSCA Title VI implementing regulations to EPA.

iii. Assigning the TPC a unique number.

b. *General responsibilities of ABs after TPC accreditation into the TSCA Title VI Third-Party Certification Program.* The EPA recognized Product AB would be responsible for:

i. Ensuring the TPC has a process in place to verify the accuracy of the formaldehyde emission tests conducted by the TPC laboratory (including any contract laboratory that the TPC would use for formaldehyde testing under TSCA Title VI) and the formaldehyde quality control tests conducted by the producers of regulated composite wood products.

ii. Ensuring the TPC has a process in place to monitor panel producer quality assurance programs.

iii. Ensuring the TPC has a process in place to conduct independent audits and inspections of panel producers and their quality control testing facilities.

iv. Conducting audits of TPCs and their laboratories.

v. Recordkeeping.

The EPA recognized Laboratory ABs would be responsible for verifying that the TPC laboratory is experienced and capable of conducting formaldehyde emissions tests according to the requirements of TSCA Title VI and its implementing regulations. The Laboratory ABs' key responsibilities would include:

- Ensuring the laboratory's conformance to the regulatory requirements, including ISO/IEC 17025:2005(E).

- Verifying the accuracy of the formaldehyde emissions tests conducted by the TPC laboratory through an inter-laboratory comparison or proficiency testing program.

- Conducting audits of the laboratory.

- Recordkeeping.

EPA proposes to require TPCs to participate in an EPA recognized inter-laboratory comparison program. If standard reference material is developed, EPA would consider requiring TPCs to participate in an EPA recognized proficiency testing program. In order to reduce duplicative requirements, EPA proposes that it would utilize the preexisting CARB-administered inter-laboratory comparison program to the extent feasible. EPA requests comment on ways it might integrate with CARB's inter-laboratory comparison program and on what criteria should be used to determine the adequacy of performance. EPA also requests comment on how participating Laboratory ABs could administer an inter-laboratory comparison program or proficiency testing program for the TPCs that it accredits. EPA would like information on the costs of such a program and whether such an activity presents conflict of interest issues for Laboratory ABs.

4. *Revocation of EPA's recognition of an AB.* EPA is proposing that it may suspend, revoke, or modify the recognition of an AB, if the AB is not complying with the requirements promulgated for ABs under TSCA Title VI. If an AB is removed or withdraws from the TSCA Title VI Third-Party Certification Program, that AB would be responsible for promptly notifying EPA and all TPCs that receive its accreditation services. If an AB is removed or withdraws from the TSCA Title VI Third-Party

Certification Program for reasons other than fraud or providing false or misleading statements related to a particular TPC or TPCs, or other than a reason that implicates a particular TPC or TPCs in a violation of TSCA Title VI or its implementing regulations, EPA proposes to allow the TPCs that were accredited by that AB to have 365 days, or 180 days if less than 365 days were left on their 3-year accreditation period, to be accredited again by another EPA recognized AB. While it is seeking accreditation from an alternate AB, a TPC would need to continue to comply with all other aspects of TSCA Title VI and its implementing regulations, and the TPC would remain subject to inspection by EPA. If an AB is removed from the TSCA Title VI Third-Party Certification Program due to fraud or providing false or misleading statements with respect to a particular TPC, or for any other reason that implicates a particular TPC in a violation of TSCA Title VI or its implementing regulations, that TPC would not be allowed to provide any TSCA Title VI certification services until it has been accredited by an alternate AB. Should this situation occur, EPA would provide notifications to the affected TPCs at the time it commences formal action against the AB. Any action EPA would take against an AB would not preclude an enforcement action against a TPC. EPA believes it is appropriate to be more stringent in these situations because the AB's nonperformance or altered status under the recognition agreement may call into question the legitimacy of the TPC's underlying accreditation. EPA requests comment on whether it has provided adequate time for a TPC to seek an alternate AB's accreditation under this proposed rule. Issues related to the de-accreditation of a TPC and the amount of time a panel producer has to seek a new TPC are discussed in Unit III.B.4.

B. Requirements for Third-Party Certifiers of Composite Wood Products

1. *Requirements to apply for participation in the TSCA Title VI Third-Party Certification Program.* EPA is proposing that the TPC must apply to an EPA recognized Product AB to certify composite wood products pursuant to TSCA Title VI. In its application to an EPA recognized Product AB, the TPC would be required to demonstrate experience and competency in certain areas that EPA believes are important in ensuring the TPC's ability to conduct audits, testing, and certification of composite wood products. The application would be reviewed by the Product AB, who would provide EPA with a copy of each application. TPC applications would provide information to document:

- a. Experience in performing or verifying formaldehyde emissions testing on composite wood products.
- b. That its laboratory or contract laboratory has been accredited by an EPA recognized Laboratory AB in conformance with ISO/IEC 17025:2005(E).
- c. The TPC laboratory's or contract laboratory's experience with test method ASTM E 1333-96 (Reapproved 2002) (Ref. 20) or successor standards and experience evaluating correlation between test methods.
- d. Experience or ability in product certification and complying with ISO/IEC Guide 65:1996(E).
- e. Experience in the composite wood product industry.
- f. The ability to inspect and properly train and supervise inspectors according to ISO/IEC 17020:1998(E).

The application would also specify which composite wood products the applicant is applying to certify and evidence that the applicant is qualified to certify these products. EPA is proposing that TPCs would be required to renew their applications every 3 years.

EPA requests comment on the costs and benefits of a 3-year renewal period as compared to a 2-year renewal period (as under the CARB ATCM). The EPA also requests comment on whether the proposed requirement for EPA-recognized ABs to audit TPCs and laboratories used by TPCs every 2 years should be extended to every 3 years to align with the proposed 3-year TPC accreditation period.

In order to facilitate communication between EPA and TPCs, EPA is proposing to require TPCs to designate an agent in United States in their applications. Any information provided by an AB or EPA to the designated agent would be equivalent to providing that information directly to the TPC. The designated agent could not be a mailbox, answering machine, or other service where the agent is not physically present. The agent would need to be capable of accepting service of notices and processes made in administrative and judicial proceedings. EPA believes requiring a designated agent in the United States would help ensure compliance with the emission standards by facilitating the ability to enforce TSCA Title VI and its implementing regulations, which in turn encourages the regulated entities to fulfill their obligations under the statute and regulations. EPA requests comment on this proposed requirement.

Title VI of TSCA requires that compliance with the formaldehyde emission standards be measured by quarterly testing using ASTM E1333-96 (Reapproved 2002) (Ref. 20) or under certain circumstances, ASTM D6007-02 (Reapproved 2008) (Ref. 21). For quality control testing, the statute requires use of ASTM D6007-02 (Reapproved 2008), ASTM D5582-00 (Reapproved 2006) (Ref. 22), or other test methods established by EPA through rulemaking. If a test method other than ASTM E1333-96 (Reapproved 2002) is used for either quarterly testing or quality control testing, TSCA Title VI

requires a demonstration of equivalence by means established by EPA. Therefore, EPA is proposing that a TPC laboratory or contract laboratory must have experience with formaldehyde testing using ASTM E1333-96 (Reapproved 2002) or its successor standards as well as experience evaluating correlations between different test methods. EPA intends to propose the means of showing test method equivalence in a subsequent proposal with other implementation provisions as required under TSCA Title VI.

EPA is proposing to require that accredited TPCs conduct the quarterly tests required by TSCA Title VI. The statute requires these tests to be performed using ASTM E1333-96 (Reapproved 2002) or, under some circumstances ASTM D6007-02 (Reapproved 2008). Section 601(d)(5) of TSCA allows EPA to substitute, after public notice and an opportunity for comment, a test method referenced in TSCA Title VI with its successor version. The version of ASTM E1333-96 (Reapproved 2002) referenced in TSCA Title VI is not the most current version. In this proposed rule, EPA is proposing to incorporate the current version, ASTM E1333-10 (Ref. 23), into the testing requirements in this proposed rule in place of ASTM E1333-96 (Reapproved 2002) referenced in the statute. EPA notes that there are only relatively minor differences between ASTM E1333-96 (Reapproved 2002) and ASTM E1333-10. For example, referenced standards have been updated to cite the most recent version of the standards. In addition, under Apparatus, *Make-up Air*, 6.1.2.2, a new requirement has been added, specifying that the dry gas test meter or other airflow rate measuring device be “permanently placed in the chamber air intake duct.” A new loading ratio was added for “low density particleboard door core” and a note specifying that “Panel grades are defined in the ANSI standards referenced in 2.3.” Under 9.2 *Conditioning*, a note was added stating “Test specimens

with low levels of formaldehyde may absorb formaldehyde from the air when the air formaldehyde content exceeds that of the test [sic] specimen. Consideration should be taken to avoid such air conditions during storage and conditioning.” In addition, the following requirement was added: “Circulation of the conditioning air shall be achieved by fans that direct air flow horizontally in the direction parallel to the primary surface of the test specimens.” Under *Test Procedure for Materials*, 10.1.3, the following phrase was deleted: “as measured by a totalizing dry gas meter permanently placed in the chamber air intake duct.” Under note 9, the following clarifying phrase was added: “unless testing is extended and chamber concentrations in air and emission rates are obtained for the tested product at multiple chamber air exchange rates or multiple product loading ratios, or both.” Under *Report the Following Information*, 12.1.7, the following was added: “and the air circulation conditions (for example, air velocity or air exchange rate.” Under (Nonmandatory Information) X1. Reagents, Materials, and Equipment Found Suitable for Use, footnotes specifying where apparatuses are available have been deleted. In addition, X1.3.2 Sulfuric Acid, has been changed from “concentrated reagent grade. Nitrate concentration shall be less than 10 ppm.” to “ACS grade. Nitrate concentration shall be no greater than 0.2 ppm.” EPA requests comment on whether ASTM E1333-10 should be incorporated into the testing requirements under TSCA Title VI in place of ASTM E1333-96 (Reapproved 2002).

EPA intends to propose the means of showing test method equivalence for other test methods as well as the number and frequency of tests required to demonstrate compliance with the formaldehyde emission standards in a subsequent proposal along with the rest of the TSCA Title VI implementing regulations. EPA is proposing here that

TPC laboratories be responsible for conducting quarterly tests, verifying quality control tests, and evaluating test method equivalence.

EPA is proposing that TPCs must have experience operating or using laboratories that follow ISO/IEC 17025:2005(E). This international voluntary consensus standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. EPA believes that requiring TPCs to use laboratories that follow these requirements would help ensure that reliable and accurate test results are obtained.

EPA is proposing that TPCs must have experience or ability in product certification and in complying with ISO/IEC Guide 65:1996(E) because certifying compliant composite wood products would be one of the main functions of a TSCA Title VI accredited TPC. ISO/IEC Guide 65:1996(E) is an international voluntary consensus standard that specifies general requirements for a third-party operating a product certification system. These general requirements would help ensure that the TPC is competent and reliable in certifying compliant composite wood products.

EPA is proposing that the TPC must have experience in conducting inspections of the manufacturers in conformity with ISO/IEC 17020:1998(E). This international voluntary consensus standard specifies general criteria for the operation of various types of bodies performing inspections. EPA is also proposing that TPCs must have the ability to properly train and supervise inspectors pursuant to conformity with ISO/IEC 17020:1998(E). Inspections by TPCs would be an important function of a TPC in helping ensure compliance with the regulations under TSCA Title VI.

EPA is proposing that TPCs must have experience in the composite wood

products industry because EPA believes that understanding the processes used by panel producers to produce composite wood products is crucial for the TPC to adequately inspect and audit panel producers. Experience in the composite wood products industry would help ensure that the TPC would know what to inspect and areas on which to focus during inspections and audits of the panel producers. In addition, EPA is proposing to require TPCs to have experience with the specific type of composite wood product(s) that it would certify. EPA believes that certain steps in the manufacture of composite wood products are likely important in maintaining low formaldehyde emissions and that because manufacturing processes are different for the different types of regulated composite wood products, it is important for a TPC to have knowledge and experience in the manufacture of the specific type of composite wood product(s) that it would certify. EPA requests comment on whether EPA should require that the TPC have experience with the specific type of composite wood product that it would certify or if experience with one type of product is sufficient to certify all types of composite wood product.

2. *Denied TPC Applicants.* If an AB denies a TPC's application for accreditation for failure to submit a complete application, the AB would be required to notify the TPC or TPC laboratory in writing of the legal and factual basis for the denial, actions, if any, which the affected TPC or TPC laboratory may take to receive accreditation in the future, and the opportunity and method for requesting a hearing with EPA. "Failure to submit a complete application" would not include failure to pay any accreditation fee or reach a fee agreement.

3. *Proposed requirements once a TPC is accredited.* EPA is proposing that once an applicant is accredited as a TPC under TSCA Title VI, the TPC must:

- a. Verify that panel producers have adequate quality assurance controls and are complying with any quality assurance and quality control requirements that EPA promulgates pursuant to TSCA Title VI.
- b. Verify quality control test results compared with ASTM E1333-10 test results by having laboratories conduct quarterly tests and evaluate test method equivalence pursuant to testing requirements promulgated under TSCA Title VI.
- c. Review applications from panel producers for reduced testing or third-party certification requirements.
- d. Establish quality control limits in consultation with panel producers, and, if applicable, shipping quality control or other limits for each product type and production line.
- e. Inform panel producers of the process that will be used to determine if product lots are exceeding the applicable quality control limit.
- f. Inspect and audit panel producers and their records at least quarterly.
- g. Use a testing laboratory or laboratories that comply with ISO/IEC 17025:2005(E).
- h. Certify composite wood product types that comply with requirements under TSCA Title VI following ISO/IEC Guide 65:1996(E).
- i. Follow ISO/IEC 17020:1998(E) in the carrying out of their inspections of the panel producers.
- j. Provide approved TPC number (supplied by the accrediting AB) to the panel producer for labeling and recordkeeping.
- k. Use laboratories that participate in an inter-laboratory comparison or

proficiency testing program.

l. Maintain records in electronic form for 3 years.

m. Provide an annual report to EPA and the AB(s) that provided it with its accreditation.

n. Inform the AB(s) that provided it with its accreditation of any changes in key personnel qualifications, procedures, or laboratories used by the TPC that could affect the TPC's ability to fulfill its obligations under this unit.

One of the main functions of TPCs under this proposed rule would be to help ensure that panel producers have adequate quality control of their manufacturing process, are following appropriate quality assurance procedures, and are complying with any quality assurance requirements that EPA may implement under TSCA Title VI. Under the CARB ATCM, manufacturers are required to implement specific quality assurance procedures as described in Appendix 2 of the ATCM. EPA anticipates promulgating quality assurance requirements for panel producers under TSCA Title VI in a subsequent proposal with other implementation provisions as required under TSCA Title VI. EPA is proposing to use TPCs to help ensure compliance with quality control and quality assurance procedures.

EPA is proposing to require TPCs to verify quality control tests that measure formaldehyde emissions by having laboratories conduct quarterly testing.

Under TSCA Title VI, EPA intends to promulgate specific formaldehyde testing requirements. The subsequent proposal may also provide for reduced testing for specified products such as those made with NAF or ULEF resins. In this proposed rule, EPA is proposing to require TPCs to review and approve, when appropriate, applications from

panel producers for reduced testing and third-party certification requirements according to EPA's implementing regulations. The CARB ATCM allows for reduced testing for products manufactured with NAF and ULEF resins, and CARB reviews and approves NAF and ULEF applications. EPA is proposing to instead require TPCs to review these applications because EPA believes they are best suited to determine whether the panel producers will be able to consistently comply with the emission standards even with reduced testing requirements. EPA intends to further specify requirements for reduced testing in a subsequent proposal with other implementation provisions as required under TSCA Title VI.

EPA is proposing to require TPC laboratories (including contract laboratories) to establish quality control limits in consultation with panel producers and, if applicable, shipping quality control or other limits for each product type and production line to ensure compliance with the emission standards. A quality control limit would be established if test methods other than ASTM E1333-10 are being used to make it easier for the panel producer to determine whether any products are likely to exceed the emission standards. A quality control limit would be the value from a test other than ASTM E1333-10 that is the correlative equivalent to the applicable standard. A TPC may also establish a limit to account for process and testing variation to help ensure that the emission for a product would not exceed the applicable standard. EPA is proposing to require TPCs to inform panel producers of the process that the TPC would use to determine if product lots are exceeding the applicable quality control limit. In the broader TSCA Title VI implementing regulations, EPA intends to describe these limits in more detail as well as implications and procedures for cases where tests exceed the limits in a

subsequent proposal with other implementation provisions as required under TSCA Title VI.

EPA is proposing to require that TPCs inspect and on-site audit panel producers and their records at least quarterly and comply with ISO/IEC 17020:1998(E) when conducting their inspections. Quarterly inspections and on-site audits are consistent with requirements under the CARB ATCM, and EPA believes that requiring inspections quarterly should be sufficiently frequent to allow TPCs to observe and mitigate any potential violations. However, under certain circumstances, a TPC could determine that more frequent inspections and on-site audits are necessary to ensure compliance. EPA requests comment on whether enhanced testing or inspection requirements should be required where a TPC finds that a panel producer has failed quality control or quarterly tests at a certain frequency, or upon other circumstances. In addition to failed test results, circumstances that EPA envisions possibly warranting increased TPC inspections and audits include a panel producer failing to comply with its quality control manual or inconsistencies in records.

EPA is proposing to require that TPCs use laboratories for formaldehyde testing that comply with ISO/IEC 17025:2005(E). As discussed in Unit II.G.1., this international voluntary consensus standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. EPA believes that requiring TPCs to use laboratories that follow these requirements would help ensure that TPCs obtain reliable and accurate test results.

EPA is proposing to require that TPCs participate in an EPA-recognized inter-laboratory comparison studies or proficiency testing, if developed. The inter-laboratory

comparisons would involve the participation of laboratories that are provided composite wood product samples to test for formaldehyde; each laboratory would test the sample using the same test method (e.g., ASTM E1333-10), and the results from all of the laboratories would be compared. If a standard reference material for formaldehyde emissions is developed, EPA proposes to require annual proficiency testing. The CARB ATCM requires laboratories to participate in an inter-laboratory comparison during the first year that the laboratory is used by a TPC, followed by participation in inter-laboratory comparisons every 2 years. EPA believes that evaluating the performance of laboratories used by the TPC by inter-laboratory comparisons or proficiency testing is vital to ensuring that laboratories are performing the formaldehyde testing properly, and EPA is therefore proposing that this be an annual requirement. EPA requests comment on whether inter-laboratory comparisons should take place more or less frequently. EPA is also seeking comment on criteria to use in evaluating performance in inter-laboratory comparisons.

EPA is proposing to require TPCs to follow ISO/IEC Guide 65:1996(E) to certify composite wood product types that comply with requirements under TSCA Title VI. As discussed in Unit II.G.1., ISO/IEC Guide 65:1996(E) is an international voluntary consensus standard that specifies general requirements for a third-party operating a product certification system. EPA believes that requiring TPCs to follow these general requirements for certifying products would help ensure that the TPC is properly certifying only compliant composite wood products.

A TPC would be supplied with a TPC identification number by the Product AB once it has been accredited for TSCA Title VI purposes. EPA is proposing to require that

the TPC provide this number to panel producers so that they can include the TPC number on the label of their certified products and include it in their records.

EPA is proposing to require TPCs to maintain records in electronic form for 3 years. TSCA Title VI directs EPA to address recordkeeping requirements in its implementing regulations and EPA believes that certain records will greatly assist the EPA in monitoring compliance with the emissions standards and other provisions. These records would be:

- A list of panel producers and their respective product types, including resins used, that the TPC has certified.
- Results of inspections, audits, and emission tests conducted for and linked to each panel producer and product type.
- A list of laboratories used by the TPC, test methods, including test conditions and conditioning time, and test results.
- Methods and results for establishing test method correlations and equivalence.

EPA is proposing to require TPCs to submit an annual report to EPA and the AB that accredits the TPC. The annual report would include:

- A list of panel producers and their products that the TPC has certified during the previous year, including resins used and the average and range of formaldehyde emissions by panel producer, resin, and product type.
- List of any non-complying products or events by panel producers.
- A list of laboratories and test methods used by the TPC.
- Results of inter-laboratory comparison or proficiency testing for the laboratories used by the TPC.

EPA is proposing to require that the TPC inform the AB(s) that accredit the TPC of any changes in key personnel qualifications, procedures, or laboratories used that could affect the TPC's ability to fulfill its obligations under this unit. EPA believes such changes could impact the TPC's ability to properly verify formaldehyde emissions, inspect and audit, and certify compliant composite wood products. EPA is proposing that the AB review the changes to determine whether the changes would impact the TPC's ability to perform its duties.

4. *Removal and reaccreditation of third-party certifiers.* EPA is proposing to exercise the authority to revoke the TSCA Title VI accreditation of a TPC or its laboratory, after notice and an opportunity for a hearing, if the TPC or its laboratory: Fails to meet any of the applicable requirements promulgated under TSCA Title VI (such as by failing to comply with ISO/IEC Guide 65:1996(E), ISO/IEC 17020:1998(E), or ISO/IEC 17025:2005(E)); makes false or misleading statements on its application, records, or reports; or makes changes to key personnel qualifications, procedures, or laboratories that would make it unable to perform its duties. ABs would also be able to revoke an accreditation of a TPC, subject to an opportunity for a hearing with EPA. A TPC whose accreditation has been revoked may reapply to an AB to be reaccredited as a TPC.

If a TPC loses its accreditation or discontinues participation in the TSCA Title VI Third-Party Certification Program for any reason, it would be responsible for promptly notifying EPA and all panel producers that it provides TSCA Title VI certification services to. If a TPC loses its accreditation or discontinues participation in the program for reasons other than fraud or providing false or misleading statements, or other than a

reason that implicates a particular panel producer in a violation of TSCA Title VI or its implementing regulations, the panel producers that used the TPC to certify their products would need to enlist another TPC to certify their products within 3 months (90 days). In these cases, the panel producers would not be required to recall or recertify their products merely because the certifying TPC lost its accreditation. During the time a panel producer is seeking a new TPC, it would need to continue to comply with all other requirements of TSCA Title VI and its implementing regulations, including quality control testing. During this period the panel producer would remain subject to inspection by EPA. If the panel producer is unable to comply with all other aspects of TSCA Title VI and its implementing regulations, the panel producer would not be permitted to sell, offer for sale, or supply its products in the United States until its products are recertified as compliant. If a TPC loses its accreditation due to fraud or providing false or misleading statements with respect to a particular panel producer, or for any other reason that implicates a particular panel producer in a violation of TSCA Title VI or the regulations promulgated thereunder, that panel producer would not be permitted to offer regulated composite wood products for sale in the United States until its composite wood products have been recertified by another TPC. If such a situation does occur, EPA would notify affected panel producer at the time it commences action against the TPC. EPA believes it is appropriate to be more stringent in these situations because the TPC's behavior may call into question the legitimacy of the manufacturer's product certification. Any action EPA would take against a TPC would not preclude an enforcement action against a panel producer. EPA requests comment on whether it has provided adequate time for a panel producer to seek an alternate certification.

C. Enforcement, Suspension, Revocation, and Modification

1. *Enforcement under TSCA sections 15-17.* EPA may conduct inspections of participating TPCs and ABs and issue subpoenas according to the requirements for accreditation and recognition and/or pursuant to the provisions of TSCA section 11 (15 U.S.C. 2610) to ensure compliance with TSCA Title VI and the regulations promulgated thereunder. Enforcement issues related to manufacturers, importers, distributors, and retailers will be covered in a subsequent proposal.

EPA would exercise the authority to withdraw from a recognition agreement with an AB and pursue penalties under TSCA section 15 (15 U.S.C. 2614) for any violation of TSCA Title VI or the regulations promulgated thereunder. In addition to an administrative or judicial finding of violation, grounds for withdrawing from a recognition agreement and/or pursuing an enforcement action against an AB include if the AB:

- Submits false or misleading information to EPA;
- Fails to maintain or falsifies required records; or
- Or otherwise fails to comply with TSCA Title VI or the regulations promulgated thereunder.

2. *Suspension, revocation and modification.* EPA would exercise the authority to suspend, revoke, or modify a TPC's TSCA Title VI accreditation, with or without the participation of the AB that provided the accreditation, if the TPC fails to comply with TSCA Title VI or the regulations promulgated thereunder. Any violation of TSCA Title VI or the regulations promulgated thereunder would also be a prohibited act under TSCA section 15. Grounds for suspending, modifying, or revoking a TPC's accreditation

include if the TPC:

- a. Submits false or misleading information to EPA or its AB;
- b. Fails to maintain or falsifies required records; or
- c. Fails to comply with TSCA Title VI or regulations promulgated thereunder.

The ISO/IEC standards and guide that are referenced in this proposed rule require that policies and procedures be in place to identify and remedy nonconformities with the implementation of those standards (ISO/IEC 17025:2005(E), section 4.9; ISO/IEC 17011:2004(E), section 5.5; ISO/IEC 17020:1998(E), section 7.8; ISO/IEC Guide 65:1996(E), section 47). Should a TPC or AB identify a nonconformity or discrepancy with its implementation of one of the ISO standards via an internal audit or other means, that entity must take remedial action within the timeframe specified by the AB or the time specified in the TPC's quality management plan in order to avoid the possibility of an enforcement action.

Prior to withdrawal from a recognition agreement with an AB, or the suspension, revocation, or modification of a TPC's accreditation, EPA would provide notification to the affected AB or TPC of:

- The legal and factual basis for the proposed action.
- The anticipated commencement date and duration of any suspension, revocation, modification, or other action.
- What actions, if any, the affected entity may take to avoid suspension, revocation, modification, or otherwise continue participation in the program.
- The opportunity and method for requesting a hearing prior to the final action.

If an individual or organization requests a hearing, EPA would:

- Provide the affected entity an opportunity to offer written statements in response to EPA's assertions of the legal and factual basis for its proposed action.

- Appoint an impartial official of EPA as Presiding Officer to conduct the hearing.

The Presiding Officer would conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing. The Presiding Officer would consider all relevant evidence, explanations, comments, and arguments submitted and notify the affected entity in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final agency action which may be subject to judicial review. The order must contain the commencement date and duration of the suspension, revocation, or modification.

If EPA determines that the public health, interest, or welfare warrants immediate action to suspend the recognition of an AB or the accreditation of a TPC prior to the opportunity for a hearing, it would notify the affected AB or TPC of its right to request a hearing on the immediate suspension within 15 days of the suspension taking place and the procedures for the conduct of such a hearing.

Any notice, decision, or order issued by EPA in response to a hearing, any transcript or other verbatim record of oral testimony, and any documents filed in response to a hearing would be available to the public, except as otherwise provided by TSCA section 14. Any such hearing at which oral testimony is presented would be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under TSCA section 14.

D. Status of CARB Approved TPCs

EPA intends to propose that the formaldehyde emissions standards in TSCA Title VI become effective 365 days after the promulgation of the TSCA Title VI implementing regulations (which are required by TSCA Title VI to be promulgated no later than January 1, 2013). EPA proposes that CARB approved TPCs would have 365 days after the promulgation of the TSCA Title VI implementing regulations to become accredited by an AB with which EPA has entered into a recognition agreement. In order to determine which TPCs are CARB approved, EPA will consult the listing of TPC's that CARB maintains on its Internet site. EPA believes that 365 days is a sufficient period of time for EPA to enter into recognition agreements with ABs and for TPCs to seek accreditation from EPA recognized ABs, ensuring no interruption in a TPC's services. During the transition period between when the final TSCA Title VI implementing regulations are promulgated and the date 365 days after promulgation, the CARB approved TPCs may carry out certification activities under TSCA Title VI provided that they are compliant with all other aspects of TSCA Title VI and the regulations promulgated thereunder. TPCs that are certifying products as compliant with TSCA Title VI are subject to inspection by EPA and enforcement actions for any violations of TSCA Title VI or the regulations promulgated thereunder. To reduce burden on existing CARB approved TPCs, the EPA requests comment on ways to better synchronize the timing for the TSCA Title VI accreditation period for existing CARB approved TPCs. For example, one option might be to extend the allowable time period for acquiring accreditation from 1 to 2 years. Another option might be to align the TSCA Title VI accreditation requirement for CARB approved TPCs with their existing CARB accreditation renewal, such that they could use the same information to be accredited by EPA and CARB at the

same time. Alternatively, the TPCs could be required to obtain accreditation from an EPA-recognized AB no later than 1 year after the first EPA-recognized AB enters into a recognition agreement with the EPA under the TSCA Title VI. EPA expects to communicate with CARB regarding its third-party certification program and to collaborate, where possible, in order to promote the mutual acceptance of TPCs.

E. Transparency

EPA has a commitment to uphold the values of transparency and openness in conducting EPA operations (Ref. 24). Transparency promotes accountability and provides information for citizens about what their government is doing (Ref. 25). EPA would support its commitment by making documentation of recognized ABs, TPCs, and panel producers available to the public. EPA is proposing to make the following information publically available on the Internet:

1. The names and addresses of all ABs that EPA has a recognition agreement with and the status of that recognition agreement.
2. A list of all accredited TPCs with their TPC number and accreditation status.
3. Annual reports from ABs.
4. A list of panel producers approved for reduced testing and reduced third-party certification requirements.

EPA requests comment on what, if any, additional information should be made publically available (e.g., annual reports from TPCs and other required notifications) and on whether there are other ways EPA might improve program transparency. EPA requests comment on whether making the following information available publically on the Internet would be useful to the public or present challenges for regulated entities:

- A list of panel producers and their products that each TPC has certified, including resins used and the average and range of formaldehyde emissions by panel producer, resin, and product type.

- A list of any non-complying products or events by panel producer.
- A list of laboratories and test methods used by each TPC.
- The results of inter-laboratory comparison or proficiency testing for the laboratories used by TPCs.

EPA requests comment on whether such information might contain CBI. EPA is considering requiring some information to be reported into a publicly viewable database, should such a database be developed. Generally, EPA is considering requiring electronic reporting of the information proposed to be reported. In particular, EPA requests comment on whether the data elements in the ABs' and TPCs' annual reports, and the required notifications should be reported into a publicly viewable database.

EPA is proposing a 3 year record retention period for all TSCA Title VI AB and TPC record keeping requirements. While EPA is proposing a 3 year record retention period as is common under the Paperwork Reduction Act, EPA requests comments on ways to reduce the burden and costs of hard-copy record keeping over multiple years on the regulated community, such as by requiring that the entities regulated under this rule be allowed to keep required records electronically and make them available to the Agency and others via their business website, or other electronic media.

Under the proposed rulemaking, composite wood products would be regulated starting with the manufacture (including import) of panels, through their incorporation into component parts and finished goods, the distribution of those products, and the retail

sale of those products. This can be a lengthy process and the amount of time composite wood panels are held in inventory and the amount of time before they are incorporated into finished goods is variable. This variability can result from prevailing economic conditions, the complexity of the individual products, the origin of the products, and other factors. This point was illustrated by the fact that CARB had to extend its “sell-through dates” multiple times. CARB found that these extensions were necessary because the recession increased the amount of time manufacturers needed to clear preexisting inventory. As CARB found that items remained in inventory for extended periods, it is possible that an issue could arise with a particular composite wood item several years after it was manufactured. Learning the source of the item may be important in order to identify and correct a problem. Because retail companies receive composite wood items from many sources and the third party certifier could vary with each item, retaining records for 3 years would help assure that problems can be identified and corrected.

Third party certifiers of compliance with formaldehyde emissions from composite wood products would need to maintain certain records long enough to assure that their oversight role in the system is operating properly to protect human health. An adequate record retention period is essential to fair and efficient enforcement of the regulatory requirements and allows EPA and interested downstream consumers to be assured that finished goods are made from compliant composite wood panels. EPA seeks to avoid the situation where records surrounding the certification of regulated products that remain available for retail sale in the United States have already been disposed of because of the passage of time. To that end, EPA requests comment on the length of time composite

wood panels may take to reach their end user, whether incorporated into a finished good or not.

EPA also requests comment on the amount of time ABs and TPCs, during their ordinary course of business, typically retain records of their accreditation or certification activities and whether this is due to any external factors such as, industry standards, customer demand, customary business practices, or other.

F. Electronic Reporting

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's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), published in the Federal Register on October 13, 2005 (70 FR 59848) (FRL-7977-1), provides that any requirement in title 40 of the Code of Federal Regulations (CFR) to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a regulation that an electronic document submission process is available for that requirement.

EPA is considering requiring information reported to EPA from TPCs and ABs be reported electronically through EPA's Central Data Exchange (CDX). CDX provides the capability for submitters to access their data through the use of web services. For more information about CDX, go to <http://epa.gov/cdx>.

Should EPA adopt a mandatory electronic reporting requirement, submitters would be required to register with EPA's CDX, complete an electronic signature agreement, and to prepare a data file for submission. 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 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 <https://cdx.epa.gov/TSCA/eTSCA-RegistrationGuide.pdf>. The registrant would also select a role and complete an electronic signature agreement either through electronic validation using the LexisNexis services or through wet ink signature. Once registration and the electronic signature agreement are complete, the user would prepare a submission.

Most of the information requested in the reporting requirements of these collections is not of a confidential nature. Nonetheless, the application would be designed to support TSCA CBI needs by providing a secure environment that meets Federal standards.

EPA is considering requiring mandatory electronic reporting requirement because such a requirement would streamline the reporting process and reduce the administrative costs associated with information submission and recordkeeping. The effort to eliminate paper-based submissions in favor of CDX reporting is part of broader government efforts to move to modern, electronic methods of information gathering. Electronic reporting allows for more efficient data transmittal and a reduction in errors with the built-in validation procedures. EPA believes the adoption of electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review. EPA requests comment on whether it should require mandatory electronic reporting. For more information on how a TSCA Title VI electronic reporting

application would function and the burdens and benefits associated with electronic reporting please see Ref. 27.

IV. Request for Comment

In addition to the areas on which EPA has specifically requested comment, EPA requests comment on all other aspects of this proposed rule.

V. References

As indicated under **ADDRESSES**, a docket has been established for this rulemaking under docket ID number EPA-HQ-OPPT-2011-0380. The following is a listing of the documents that are specifically referenced in this action. 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. Public Law 111-199, Title VI--Formaldehyde Standards for Composite Wood Products Act, enacted July 7, 2010. (TSCA section 601(d), 15 U.S.C. 2601 *et seq.*)
2. Agency for Toxic Substances and Disease Registry (ATSDR). 1999. Toxicological Profile for Formaldehyde and 2010 Addendum to the Profile. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.
3. National Toxicology Program, U.S. Department of Health and Human Services (HHS), 12th Report on Carcinogens, June 10, 2011.
4. EPA, ORD. Integrated Risk Information System (IRIS) Program. IRIS Toxicological Review of Formaldehyde-Inhalation Assessment (2010 External Review

Draft). Available online at:

http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.

5. National Academy of Sciences (NAS). Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. 2011. Available online at:

http://www.nap.edu/catalog.php?record_id=13142.

6. International Agency for Research on Cancer (June 2006). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 88 (2006): Formaldehyde, 2-Butoxyethanol and 1-tert-Butoxypropan-2-ol

7. California Environmental Protection Agency Air Resource Board. *CARB Airborne Toxic Control Measure*. April 26, 2007. Available online at:

<http://www.arb.ca.gov/toxics/compwood/compwood.htm>.

8. California Environmental Protection Agency Air Resources Board, Composite Wood Products ATCM, List of CARB Approved Third-party Certifiers (Accessed August, 2011). Available online at:

<http://www.arb.ca.gov/toxics/compwood/listoftpcs.htm>.

9. California Environmental Protection Agency Air Resources Board, Application to be a Third-party Certifier (TPC) of Composite Wood Products. Available online at:

<http://www.arb.ca.gov/toxics/compwood/tpc/tpcapplication.pdf>.

10. Sierra Club. Citizen Petition to EPA Regarding Formaldehyde in Wood Products. March 20, 2008. Available online at:

<http://www.epa.gov/opptintr/chemtest/formaldehyde/index.html>.

11. EPA. Formaldehyde Emissions from Composite Wood Products; Disposition of TSCA Section 21 Petition. **Federal Register**. (73 FR 36504, June 27, 2008) (FRL-8371-5).

12. EPA. Formaldehyde Emissions from Composite Wood Products; Advanced notice of proposed rulemaking and notice of public meetings. **Federal Register**. (73 FR 73620, December 3, 2008) (FRL-8386-3).

13. ISO/IEC Guide 65:1996(E), General Requirements for Bodies Operating Product Certification Systems (First Edition) 1996.

14. ISO/IEC 17011:2004(E), Conformity Assessments--General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005.

15. ISO/IEC 17025:2005(E), General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005.

16. ISO/IEC 17020:1998(E), General Criteria for the Operation of Various Types of Bodies Performing Inspections (First Edition) November 15, 1998.

17. International Accreditation Forum. Available online at: <http://www.iaf.nu/>.

18. International Laboratory Accreditation Cooperation. Available online at: <http://www.ilac.org>.

19. EPA. National Lead Laboratory Accreditation (NLLAP). Available at: <http://www.epa.gov/lead/pubs/nllap.htm>.

20. ASTM E1333-96 (Reapproved 2002). Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber.

21. ASTM D6007-02 (Reapproved 2008), October 1, 2008. Standard Test Method for Determining Formaldehyde Concentrations in Air from Wood Products Using a Small-Scale Chamber.

22. ASTM D5582-00 (Reapproved 2006), October 1, 2006. Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator.

23. ASTM E1333-10 (May 1, 2010). Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber.

24. EPA. Memorandum from Lisa Jackson to EPA Employees (April 23, 2009). Available online at: <http://www.epa.gov/Administrator/operationsmemo.html>.

25. Memorandum from President Barack Obama to the Heads of Executive Departments and Agencies. January 21, 2009. Available online at: http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment.

26. EPA. Economic Analysis of the Third-Party Certification Framework for the Formaldehyde Standards for Composite Wood Products Act Proposed Rule (Economic Analysis). May 2013.

27. EPA. Information Collection Request (ICR) for the Formaldehyde Emissions From Composite Wood Products, Third-Party Certification Framework, Recordkeeping and Reporting; Proposed Rule, (RIN 2070-AJ44). EPA ICR No. 2441.01 and OMB No. 2070-[NEW]. May 2013.

28. EPA. Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Implementing the Formaldehyde Standards for Composite Wood Products Act (TSCA Title VI). April 4, 2011.

VI. Statutory and Executive Order Reviews

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

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this is a “significant regulatory action” because it may raise novel legal or policy issues related to the establishment of a new regulatory program as mandated by a new statutory amendment. Accordingly, EPA submitted this proposed rule to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket for this proposed rule.

EPA prepared an analysis of the potential costs and benefits associated with this action. A copy of this Economic Analysis (Ref. 26) is available in the docket for this proposed and the analysis is briefly summarized here.

This proposed rule would require ABs to submit an application and enter into a recognition agreement with EPA, provide notifications and annual reports, and maintain records. A typical AB is estimated to incur an annualized cost of nearly \$800 per year. For the purposes of cost estimation EPA assumes that eight organizations in the United States will become ABs in the TSCA Title VI Third-Party Certification Program, so total costs to U.S. ABs are estimated to be approximately \$6,300 per year.

This proposed rule would require TPCs to submit an application, submit notifications and annual reports, and maintain records. These requirements are estimated to cost an average TPC about \$1,100 per year. The proposed rule also would require TPCs to be accredited for certain ISO/IEC guide and standards. Most potential TPCs that are likely to participate in the TSCA Title VI Third-Party Certification Program are

expected to already have all the necessary accreditations, but some TPCs are assumed to need an additional accreditation at a cost of \$25,000 in the first year and \$5,000 per year in subsequent years. For the purposes of cost estimation EPA assumes that there will be nine U.S. TPCs under this proposed rule. Total costs to U.S. TPCs due to the proposed rule are estimated to be approximately \$94,000 in the first year and \$24,000 to \$28,000 per year in subsequent years. Annualized costs to U.S. TPCs are \$27,000 and \$28,000 per year, using a 3% and 7% discount rate, respectively.

The combined total cost for accreditation bodies and TPCs is estimated to be \$107,000 in the first year. Annualized costs are estimated at approximately \$34,000 per year using either a 3% or 7% discount rate.

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The ICR document prepared by EPA has been assigned EPA ICR No. 2441.01.

This proposed rule would require TPCs to provide EPA and ABs with pertinent information necessary for accreditation. Also, this proposed rule would require ABs to provide EPA with necessary information through a recognition agreement in order to qualify them to function as an AB pursuant to the regulations. EPA has therefore prepared and submitted to OMB an ICR document entitled “Formaldehyde Emissions From Composite Wood Products, Third-Party Certification Framework, Recordkeeping and Reporting; Proposed Rule (RIN 2070-AJ44),” identified under EPA ICR No. 2441.01 and OMB Control No. 2070-[NEW], which is also available for review in the docket for this proposed rule (Ref. 27). The ICR describes the information collection activities and

the estimated burden hours and costs, which are briefly summarized here.

Because the approval requirements for information collection requests under PRA is not limited to U.S. entities, the reporting and recordkeeping burden of the proposed rule is calculated for both foreign and domestic entities.

The average reporting and recordkeeping burden for ABs is estimated at approximately 21 hours per year. EPA assumes that 8 U.S. ABs and 17 foreign ABs will participate in the TSCA Title VI program, so the annual burden for ABs is estimated to be 500 hours. The average reporting and recordkeeping burden for TPCs is estimated at approximately 25 hours per year. EPA assumes there will be nine domestic TPCs and 27 foreign TPCs that participate in the TCA Title VI program, so the annual burden for ABs is estimated at approximately 900 hours. Total respondent burden for ABs and TPCs combined is estimated at approximately 1,400 hours per year. The total cost to United States and foreign TPCs that need to obtain additional accreditation is estimated to average \$140,000 per year. Burden is defined at 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations codified in title 40 of the Code of Federal Regulations, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

To comment on the Agency's need for this information, the accuracy of the

provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this proposed rule, which includes this ICR, under docket ID number EPA-HQ-OPPT-2011-0380. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** at the beginning of this proposed rule for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, ATTN: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after [*insert date of publication in the Federal Register*], a comment to OMB is best assured of having its full effect if OMB receives it by [*insert date 30 days after date of publication in the Federal Register*]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act, 5 U.S.C. 553, or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, a small entity is defined as:

1. A small business, as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201. The SBA's definitions typically are based upon either a

sales or an employment level, depending on the nature of the industry.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Since the regulated community does not include small governmental jurisdictions, the Agency's analysis focuses on small businesses and small non-profits organizations.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in the Economic Analysis (Ref. 26).

EPA evaluated two factors in its analysis of the proposed rule's requirements on small entities, the number and type of small entities potentially affected, and the extent of the rule's potential economic impact on those entities as measured by the cost-to-revenue ratio for businesses and the cost-to-expenses ratio for non-profit organizations. This ratio is a good measure of entities' ability to afford the costs attributable to a regulatory requirement, because comparing compliance costs to revenues or expenses provides a reasonable indication of the magnitude of the regulatory burden relative to a commonly available measure of economic activity. Where regulatory costs represent a small fraction of a typical entity's revenues or expenses, the financial impacts of the regulation on such entities may be considered as not significant. The impact ratios were calculated using annualized costs, because these costs are more representative of the continuing costs entities would face to comply with this proposed rule.

EPA assumed that 5 small non-profit organizations and 4 small businesses in the United States will participate as ABs or TPCs in the TSCA Title VI program. All of the small non-profit organizations are expected to have cost impacts below the 1% level. Three of the small businesses are expected to have cost impacts below the 1% level, and one is expected to have cost impacts between 1% and 3%. So of the 9 total small entities assumed to be affected by the final rule, 8 are expected to have impacts under 1%, and 1 is expected to have impacts between 1% and 3%.

In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency. EPA solicits comments specifically about the potential economic impacts that this proposed rule may impose on small entities.

Although not required by RFA to convene a Small Business Advocacy Review (SBAR) Panel for this particular proposed rule because EPA has determined that this proposal would not have a significant economic impacts on a substantial number of small entities, EPA convened a SBAR Panel to obtain advice and recommendations from small entities representatives potentially subject to the proposed rule's requirements. The SBAR Panel covered the proposed regulations and the broader TSCA Title VI implementing regulations proposal which will follow. The SBAR Panel was convened by EPA's Small Business Advocacy Chairperson on February 3, 2011. In addition to the chairperson, the Panel consisted of the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the SBA.

Seventeen potentially impacted small entities served as Small Entity

Representatives (SERs), representing a broad range of small entities from diverse geographic locations and five association representatives. EPA hosted two meetings with the SERs to obtain feedback. During the Pre-Panel Outreach Meeting on January 6, 2011, and the Panel Outreach Meeting on February 17, 2011, EPA reviewed the major areas of regulation, including options for the proposed framework of the TSCA Title VI Third-Party Certification Program, with the SBAR Panel and the SERs. The SBAR Panel solicited comments from the SERs on the options presented by EPA, their experiences with the CARB ATCM, any additional concerns they might have, and the costs of regulatory options. Several SERs submitted written comments to EPA following the meetings. The Panel evaluated the assembled materials and small entity comments on issues related to the elements of an IRFA. A copy of the SBAR Panel report is included in the docket for this proposed rule (Ref. 28). As a result of its deliberations, the Panel made a number of recommendations. With regards to the proposed TSCA Title VI Third-Party Certification Program, the Panel recommended that EPA continue to explore how it can capitalize on the expertise of international ABs, while at the same time maintaining control over the design and implementation of its certification system.

D. Unfunded Mandates Reform Act (UMRA)

Title II of UMRA, 2 U.S.C. 1531-1538, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, or tribal governments, in the aggregate, or the private sector in any 1 year. No State, local, or tribal governments currently acts as accreditation bodies or TPCs, and none are

anticipated to do so in the future, so the proposed rule would not result in expenditures by these government bodies. The costs of the proposed rule to the private sector are expected to be approximately \$100,000 in the first year, and significantly less costly in subsequent years. Thus, this proposed rule is not subject to the requirements of UMRA sections 202 or 205. This proposed rule is also not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments. Since no State, local, or tribal governments are expected to act as accreditation bodies or TPCs.

E. Executive Order 13132: Federalism

This action does not have federalism implications 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). No States are expected to act as accreditation bodies or TPCs, and EPA would administer these requirements not the States. The proposed rule would not impose substantial direct compliance costs on States. Furthermore, the proposed rule would not preempt State or local law. Thus, Executive Order 13132 does not apply to this action. Nonetheless, since California also has a program to regulate formaldehyde emissions from composite wood products, EPA held numerous consultations with representatives of the California Air Resources Board while developing this proposed rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits

comments on this proposed action from State and local officials.

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). No Tribes are expected to act as accreditation bodies or TPCs, and EPA would administer these requirements not Tribes. Thus, Executive Order 13175 does not apply to this action. EPA specifically solicits additional comment on this proposed action from tribal officials.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045, because it would not establish an environmental standard intended to mitigate health or safety 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 the supply, distribution, or use of energy. Further, we have concluded that this rule is not likely to have any adverse energy affects because it sets up a framework for a TSCA Title VI Third-Party Certification Program, and does not require any action related to the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA, 15 U.S.C. 272 note, directs EPA to use voluntary

consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule involves technical standards. EPA proposes to use voluntary consensus standards. The proposed framework of this TSCA Title VI Third-Party Certification Program is based on the ability of ABs to review TPCs for their conformity to ISO/IEC Guide 65:1996(E), ISO/IEC 17025:2005(E), and ISO/IEC 17020:1998(E). Both Product ABs and Laboratory ABs would be required to maintain their conformity to ISO/IEC 17011:2004(E).

EPA welcomes comments on this aspect of the proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the final rule.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high

and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This proposed rule would establish a system whereby ABs accredits TPCs, and TPCs certify composite wood products in order to ensure compliance with the emissions standards in TSCA Title VI. This proposed rule does not relax a pollution control measure and therefore will not cause emissions increases.

List of Subjects in 40 CFR Part 770

Environmental protection, Composite wood products, Formaldehyde, Reporting and recordkeeping, Third-party certification.

Dated: May 23, 2013.

Bob Perciasepe, Acting Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended by adding a new part 770 to read as follows:

PART 770--FORMALDEHYDE STANDARDS FOR COMPOSITE WOOD PRODUCTS

Subpart A--General Provisions

Sec.

770.1 Scope and applicability.

770.2 Effective dates.

770.3 Definitions.

Subpart B--TSCA Title VI Third-Party Certification Program

770.7 Third-party certification.

770.9 Prohibited Acts.

Subpart C--[Reserved]

Subpart D--Incorporation by Reference

770.99 Incorporation by reference.

Authority: 15 U.S.C. 2697(d).

Subpart A--General Provisions

§ 770.1 Scope and applicability.

(a) This subpart applies to:

(1) Laboratory Accreditation Bodies (ABs) and Product ABs that are accrediting third-party certifiers (TPCs) for TSCA Title VI (15 U.S.C. 2697(d)) purposes and those that wish to commence accrediting third-party certifiers for TSCA Title VI purposes.

(2) TPCs that are certifying composite wood products for TSCA Title VI compliance and those that wish to commence certifying composite wood products for TSCA Title VI compliance.

(b) [Reserved]

§ 770.2 Effective dates.

(a) Laboratory and Product ABs that wish to accredit TPCs for TSCA Title VI

purposes may apply to EPA to become recognized beginning on [*date of publication of the final rule in the **Federal Register***]. Laboratory and Product ABs must be recognized by EPA before they begin providing TSCA Title VI accreditation services.

(b) TPCs that wish to provide TSCA Title VI certification services must meet all the requirements of this subpart before they commence providing TSCA Title VI certification services.

(c) Notwithstanding any other provision of this subpart, TPCs that are approved by the California Air Resources Board to certify composite wood products have until [*date 1 year after date of publication of the final rule in the **Federal Register***] to become accredited pursuant to the requirements of this subpart. During the year following [*date of publication of the final rule in the **Federal Register***], the California Air Resources Board-approved TPCs may carry out certification activities under TSCA Title VI, provided that they are compliant with all other aspects of TSCA Title VI and the regulations promulgated thereunder. Third-party certifiers that are certifying products as compliant with TSCA Title VI are subject to enforcement actions for any violations of TSCA Title VI or the regulations promulgated thereunder.

§ 770.3 Definitions.

For purposes of this part:

Accreditation Body or *AB* means an organization that provides an impartial verification of the competency of conformity assessment bodies such as TPCs.

Composite wood product means hardwood plywood, medium-density fiberboard, and particleboard.

EPA Recognized Laboratory Accreditation Body or *EPA Recognized Laboratory AB* means a Laboratory AB that has a recognition agreement with EPA under the TSCA Title VI Third-Party Certification Program.

EPA Recognized Product Accreditation Body or *EPA Recognized Product AB* means a Product AB that has a recognition agreement with EPA under the TSCA Title VI Third-Party Certification Program.

Laboratory Accreditation Body or *Laboratory AB* means an accreditation body that accredits laboratories to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99).

Panel producer means a manufacturing plant or other facility that manufactures (excluding imports) hardwood plywood, particle board, or medium density fiberboard.

Product Accreditation Body or *Product AB* means an accreditation body that accredits conformity assessment bodies to ISO/IEC Guide 65:1996(E) (incorporated by reference, see § 770.99) and ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99).

TSCA Title VI Accredited Third-Party Certifier or *TSCA Title VI Accredited TPC* means an organization or entity that is accredited by an EPA recognized Product AB and an EPA recognized Laboratory AB pursuant to § 770.7(c)(1).

Subpart B--TSCA Title VI Third-Party Certification Program

§ 770.7 Third-party certification.

(a) *Product ABs--(1) Qualifications.* To apply to be recognized by EPA as a Product AB, a candidate Product AB must:

- (i) Be a signatory to the International Accreditation Forum, Inc.'s (IAF)

Multilateral Recognition Arrangement (MLA) through level 3, or an equivalent organization.

(ii) Be in conformance with ISO/IEC 17011:2004(E) (incorporated by reference, see § 770.99) and maintain that conformity.

(iii) Demonstrate basic competence to perform accreditation activities for product certification according to ISO/IEC Guide 65:1996(E) (incorporated by reference, see § 770.99).

(iv) Demonstrate competence to perform accreditation activities for inspection certification according to ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99).

(2) *Recognition.* To be recognized by EPA, a Product AB must apply to EPA by fulfilling the requirements in the paragraphs (a)(2)(i) through (ii) of this section:

(i) Submitting an application to the EPA with the following information:

(A) Name, address, telephone number, and email address of primary contact.

(B) Documentation of its IAF MLA signatory status, or equivalent.

(C) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the AB or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this subpart.

(D) Description of any other qualifications related to its experience in performing product accreditation of conformity assessment bodies or TPCs of manufactured products.

(ii) Entering into a recognition agreement with EPA that describes the Product

AB's responsibilities under this subpart.

(A) Each recognition agreement will be valid for 3 years.

(B) To renew a recognition agreement for additional 3 year periods, the Product AB must submit an application for renewal (before the 3 year period of the recognition agreement lapses) that indicates any changes from the Product AB's initial application.

(C) If a Product AB fails to submit an application for renewal prior to the expiration of the previous recognition agreement, its recognition will lapse and the Product AB may not provide TSCA Title VI accreditation services.

(D) If the Product AB does submit an application for renewal prior to the expiration of the previous recognition agreement, it may continue to provide TSCA Title VI accreditation services under the terms of its previous recognition agreement until EPA has taken action on its application for renewal of the recognition agreement.

(3) *Responsibilities*. EPA recognized Product ABs must fulfill the requirements in paragraphs (a)(3)(i) through (xiv) of this section:

(i) Receive and act on applications for accreditation from TPCs.

(ii) Assign a unique number to each accredited TPC.

(iii) Forward a copy of a TPC's application for TSCA Title VI accreditation to EPA at the address identified in the recognition agreement within 90 days of the date of receipt.

(iv) Perform an in-depth systems audit, as described in this unit, on each TPC applicant who submits a complete application at the time of initial application. The systems audit must include the components described in paragraphs (a)(3)(iv)(A) through (F) of this section:

(A) An on-site assessment by the Product AB to determine whether the TPC applicant's program requirements are consistent with ISO/IEC Guide 65:1996(E) and ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99). The Product AB must develop a checklist that lists all of the key conformity elements of ISO/IEC Guide 65:1996(E) and ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99) and the Product ABs must use the checklist for each on-site assessment.

(B) A review of the approach that the TPC applicant will use to verify the accuracy of the formaldehyde emissions tests conducted by the TPC laboratory or contract laboratory and the formaldehyde quality control tests conducted by the panel producers producing composite wood products that are subject to the requirements of TSCA Title VI.

(C) A review of the approach that the TPC applicant will use for evaluating a panel producer's quality assurance and quality control processes, the qualifications of the panel producer's quality assurance and quality control personnel, the required elements of a panel producer's quality assurance and quality control manual, and sufficiency of on-site testing facilities as applicable.

(D) A review of the approach that the TPC applicant's laboratory will use for establishing correlation or equivalence between alternative formaldehyde test methods and ASTM E1333-10 (incorporated by reference, see § 770.99).

(E) A review of the approach that the TPC applicant will use for evaluating the process for sample selection, handling, and shipping procedures, if applicable, that the panel producer will use for quality control testing.

(F) A review of the accreditation credentials of the laboratory that the TPC

applicant will use. The review must ensure that the laboratory has been accredited to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99) by a Laboratory AB that is a signatory to the ILAC MRA or equivalent.

(v) Upon request, allow EPA representatives to accompany its assessors during an on-site assessment to observe the audit of a TPC.

(vi) Accredite TPCs that submit a complete application as described in § 770.7(c)(1)(i) and that meet the requirements of § 770.7(c).

(vii) Conduct a follow-up systems audit, including an on-site assessment, of each TPC that the AB has accredited at least every 2 years.

(viii) Suspend, modify, or revoke the accreditation of a TPC in accordance with § 770.7(e).

(ix) Provide written notifications to EPA at the address identified in the recognition agreement, as follows:

(A) Notification of loss of its status as a signatory to the IAF MLA (or membership in an equivalent organization) must be provided to EPA within 5 business days of the date that the body receives notification of the loss of its signatory status.

(B) Notification of the TSCA Title VI accreditation of a TPC must be provided to EPA within 5 business days of the date that the TPC is accredited.

(C) Notification that an accredited TPC has failed to comply with any provision of this section must be provided to EPA within 24 hours of the time the Product AB identifies the failure.

(D) Notification of suspension or revocation of a TPC's accreditation must be provided to EPA within 24 hours of the time that the suspension or revocation takes

effect.

(E) Notification of a decision to make changes in its organizational policies or management structure that could adversely affect the TPC accreditation program must be provided to EPA within 30 days of the decision to make the changes.

(x) If the Product AB is removed or withdraws from the TSCA Title VI Third-Party Certification Program, notification must be given to all of the TPCs that receive its accreditation services within 5 business days.

(xi) Maintain the checklists and other records documenting compliance with the requirements for systems audits and on-site assessments of TPCs for 3 years. These records must be in electronic form, and the Product AB must provide them to EPA within 30 days upon request.

(xii) Provide a report to EPA at least once each year (12 months from the anniversary of the date of the recognition agreement), that includes the number and locations of systems audits and on-site assessments performed.

(xiii) Meet with EPA at least once every 2 years to discuss the implementation of the TPC accreditation program.

(xiv) Allow inspections by EPA, conducted at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and a written notification to the Product AB.

(b) *Laboratory ABs*--(1) *Qualifications*. To apply to be recognized by EPA as a Laboratory AB, a candidate Laboratory AB must:

(i) Be a signatory to the ILAC MRA, or an equivalent organization.

(ii) Be in conformance with ISO/IEC 17011:2004(E) (incorporated by reference.

see § 770.99) and maintain that conformity.

(iii) Demonstrate competence to perform accreditation activities for laboratory accreditation according to ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99).

(2) *Recognition.* To be recognized by EPA, a Laboratory AB must apply to EPA by fulfilling the requirements in paragraphs (b)(2)(i) through (ii) of this section:

(i) Submit an application to the EPA with the information listed in paragraphs (b)(2)(i)(A) through (D) of this section (if the accreditation body is also applying to be recognized as a Product AB, this application may be submitted in conjunction with the Product AB application):

(A) Name, address, telephone number, and email address of primary contact.

(B) Documentation of ILAC MRA signatory status, or equivalent.

(C) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the AB or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this subpart.

(D) Description of any other qualifications related to the Laboratory AB's experience in performing laboratory accreditation and inspection certification of conformity assessment bodies or TPCs.

(ii) Enter into a recognition agreement with EPA that describes the Laboratory AB's responsibilities under this subpart.

(A) Each recognition agreement will be valid for 3 years.

(B) To renew a recognition agreement for additional 3 year periods, the

Laboratory AB must submit an application for renewal (before the 3 year period of the recognition agreement lapses) that indicates any changes from the Laboratory AB's initial application.

(C) If the Laboratory AB does submit an application for renewal prior to the expiration of the previous recognition agreement, it may continue to provide TSCA Title VI accreditation services under the terms of its previous recognition agreement until EPA has taken action on its application for renewal of the recognition agreement.

(3) *Responsibilities*. EPA recognized Laboratory ABs must fulfill the requirements in paragraphs (b)(3)(i) through (xiii) of this section:

(i) Receive and act on applications for laboratory accreditation from TPC laboratories (including contract laboratories).

(ii) Within 15 days of a request by a TPC or their EPA recognized Product AB, forward copies of a TPC's TSCA Title VI laboratory application and accreditation documentation to the applicable EPA recognized Product AB (if the Laboratory AB is not also recognized as a Product AB) at the address identified by the TPC.

(iii) Perform an in-depth systems audit on the laboratory of each TPC applicant who submits a complete application at the time of initial application. The systems audit must include:

(A) An on-site assessment by the Laboratory AB to determine whether the TPC applicant's laboratory is consistent with all regulatory requirements and ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99).

(B) Include a checklist that lists all of the key conformity elements of ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99) and the Laboratory AB's

assessors must use the checklist for each on-site assessment.

(iv) Upon request, allow EPA representatives to accompany its assessors during an on-site assessment to observe the audit of a TPC.

(v) Accredite laboratories that submit a complete application as described in § 770.7(c)(1)(ii) and that continue to meet the requirements of § 770.7(c).

(vi) Verify the accuracy of the formaldehyde emissions tests conducted by the TPC laboratory through an inter-laboratory comparison or proficiency testing program if available.

(vii) Conduct a follow-up systems audit at least every 2 years, including an on-site assessment, of each TPC laboratory that the accreditation body has accredited. TPCs' laboratories that have not adequately performed an inter-laboratory comparison or proficiency testing must be audited at least once each year for a period of 2 years from the date of the latest poor proficiency test or inter-laboratory comparison.

(viii) Suspend, modify, or revoke the accreditation of TPCs' laboratories in accordance with § 770.7(e).

(ix) Provide the following written notifications to EPA and to the applicable EPA recognized Product AB (if the Laboratory AB is not also recognized as a Product AB) at the address identified in the recognition agreement:

(A) Notification of loss of its status as a signatory to the ILAC MRA, or membership in an equivalent organization, must be provided within 5 business days of the date that the body receives notice of the loss of its signatory status.

(B) Notice of accreditation of a TPC's laboratory must be provided within 5 business days of the date that the laboratory is accredited.

(C) Notice that an accredited laboratory has failed to comply with any provision of this section must be provided within 24 hours of the time the Laboratory AB identifies the failure.

(D) Notice that an accredited TPC has failed to comply with any provision of this section must be provided within 24 hours of the time the Laboratory AB identifies the failure.

(E) Notice of a decision to make changes in its organizational policies or management structure that could adversely affect the laboratory accreditation program must be provided to EPA within 30 days of the decision to make the changes.

(F) Notice if the Laboratory AB suspends or revokes a laboratory's accreditation must be provided within 24 hours of the time that the suspension or revocation takes effect.

(x) Maintain checklists and other records documenting compliance with the requirements for systems audits and on-site assessments of laboratories must be retained for 3 years. These records must be in electronic form and provided to EPA within 30 days of request.

(xi) Provide a report to EPA at least once each year (12 months from the date of the recognition agreement) that includes the following information:

(A) The names and contact information of all the TSCA Title VI accredited TPC laboratories.

(B) Number and locations of systems audits and on-site assessments performed.

(C) Results of inter-laboratory comparisons or proficiency testing for each of the AB's TSCA Title VI accredited TPC laboratories, if such an EPA recognized inter-

laboratory comparisons or proficiency testing program is available.

(xii) Meet with EPA at least once every 2 years to discuss the implementation of the laboratory accreditation program.

(xiii) Allow inspections by EPA, conducted at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and written notice to the laboratory accreditation body.

(c) *Third-party certifiers--(1) Qualifications.* In order to participate as a TPC of composite wood products under TSCA Title VI, a TPC must apply to an EPA recognized Product AB. In its application the TPC must demonstrate that it has been accredited by an EPA recognized Laboratory AB, unless the TPC is applying to an EPA recognized Product AB that is also an EPA recognized Laboratory AB and the TPC is seeking both accreditations from this single AB. In such a case, the TPC will obtain the required product and laboratory accreditations pursuant to ISO/IEC Guide 65:1996(E) and ISO/IEC 17025:2005(E), respectively, from the EPA recognized Product AB.

(i) To participate in the TSCA Title VI Third-Party Certification Program, a TPC must submit an application to an EPA recognized Product AB every 3 years that includes the elements in paragraphs (c)(1)(i)(A) through (D) of this section:

(A) Name, address, telephone number, and email address of primary contact.

(B) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the TPC or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this subpart.

(C) Type of composite wood products that the applicant intends to certify if accredited.

(D) Description of the TPC's qualifications, including indications that the TPC has:

(1) Experience or ability in product certification and complying with ISO/IEC Guide 65:1996(E) (incorporated by reference, see § 770.99).

(2) Experience in the composite wood product industry with the specific product(s) the applicant intends to certify.

(3) Ability to conduct inspections and properly train and supervise inspectors pursuant to ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99).

(ii) To be accredited by a laboratory accreditation body under TSCA Title VI, a TPC or its laboratories must submit an application to an EPA recognized Laboratory AB every 3 years that includes the elements in paragraphs (c)(1)(ii)(A) through (C) of this section:

(A) Name, address, telephone number, and email address of primary contact.

(B) If not a domestic entity, name and address of an agent for service located in the United States. Service on this agent constitutes service on the TPC or any of its officers or employees for any action by EPA or otherwise by the United States related to the requirements of this subpart.

(C) Description of the TPC's laboratory's qualifications, including indications that the TPC's laboratory has:

(1) Experience in performing or verifying formaldehyde testing on composite wood products.

(2) Experience complying with ISO/IEC 17025:2005(E) (incorporated by reference, see § 770.99).

(3) Experience with test method ASTM E1333-10 (incorporated by reference, see § 770.99) and experience evaluating correlation between test methods.

(2) *Responsibilities.* To maintain participation in the TPC TSCA Title VI program, TSCA Title VI accredited TPCs must fulfill the requirements in paragraphs (c)(2)(i) through (xvi) of this section:

(i) Verify that panel producers have adequate quality assurance and quality control procedures and are complying with applicable quality assurance and quality control requirements pursuant to TSCA Title VI, including the requirements of this subpart.

(ii) Verify quality control test results compared with ASTM E1333-10 (incorporated by reference, see § 770.99) test results by having TPC laboratories conduct quarterly tests and evaluate test method equivalence.

(iii) Review applications from panel producers for reduced testing, approve an application within 90 days of receipt if it demonstrates that the requirements for reduced testing under TSCA Title VI are met, and notify EPA of all approvals for reduced testing within 5 days of the approval, and forward copies of all approved applications for reduced test to EPA within 30 days of receipt.

(iv) Establish quality control limits in consultation with panel producers and, if applicable, shipping quality control or other limits for each panel producer, product type, and production line.

(v) Establish for each panel producer the process that will be used to determine if

product lots are exceeding the applicable quality control limit.

(vi) Inspect and audit panel producers and products and their records at least quarterly and pursuant to ISO/IEC 17020:1998(E) (incorporated by reference, see § 770.99).

(vii) Use only laboratories that have been accredited by an EPA recognized Laboratory AB and participate in an EPA-approved inter-laboratory comparison or proficiency testing program and ensure the results of the EPA-approved inter-laboratory comparison or proficiency testing program are provided to the Laboratory AB.

(viii) Certify composite wood product types that comply with the emission standards of TSCA Title VI and this subpart, following ISO/IEC Guide 65:1996(E) (incorporated by reference, see § 770.99).

(ix) Provide its accreditation number to the panel producer for labeling and recordkeeping.

(x) Maintain the following records, in electronic form, for 3 years from the date the record is created, and provide them to EPA within 30 days of the request:

(A) A list of panel producers and their respective product types, including resins used, that the TPC has certified.

(B) Results of inspections, audits, and emission tests conducted for and linked to each panel producer and product type.

(C) A list of laboratories used by the TPC, as well as test methods, including test conditions and conditioning time, and test results.

(D) Methods and results for establishing test method correlations and equivalence.

(xi) Provide an annual report to its accreditation body or bodies (Product AB and

Laboratory AB) and to EPA that contains the following:

(A) A list of panel producers and their products that the TPC has certified during the previous year, including resins used and the average and range of formaldehyde emissions by panel producer, resin, and product type.

(B) A list of any non-complying products or events by panel producers.

(C) A list of laboratories and test methods used by the TPC.

(xii) Inform its accreditation body or bodies (Product AB and Laboratory AB) within 30 days of any changes in personnel qualifications, procedures, or laboratories used by the TPC.

(xiii) Allow inspections by EPA, conducted at reasonable times, within reasonable limits, and in a reasonable manner, upon the presentation of appropriate credentials and of a written notice to the TPC.

(xiv) If not a domestic entity, the TPC must maintain an agent for service located in the United States and notify EPA of any changes in the name or address of that agent within 5 business days.

(xv) Participate an inter-laboratory comparison or proficiency testing program annually, or use only contract laboratories that participate in such a program.

(xvi) If a TPC or its laboratory loses its accreditation or discontinues participation in the program for any reason, it must notify EPA and all the panel producers it provides TSCA Title VI certification services to within 3 business days.

(d) *Third-party certifiers approved by the California Air Resources Board.* TPCs approved by the California Air Resources Board as of [date 60 days after date of publication of the final rule in the **Federal Register**] may certify composite wood

products under TSCA Title VI until [*date 1 year after date of publication of the final rule in the **Federal Register***] as long as they remain approved by the California Air Resources Board for that period and comply with all aspects of this subpart other than the accreditation requirements of paragraph (c)(1) of this section. In lieu of the accreditation number required to be provided according to paragraph (c)(2)(ix) of this section, a TPC approved by CARB according to this section must provide the panel producer with the TPC number issued by CARB. For a TPC approved by CARB according to this section, the annual report under paragraph (c)(2)(xi) of this section must be provided to CARB in lieu of the AB. After [*date 1 year after date of publication of the final rule in the **Federal Register***], no TPC may certify composite wood products under TSCA Title VI unless the TPC is accredited in accordance with paragraph (c)(1) of this section.

(e) *Suspension, revocation, or modification of recognition or accreditation--(1)*
Third-party certifiers. EPA or an AB may suspend, revoke, or modify the accreditation of a TPC or a TPC laboratory, if the TPC or TPC laboratory:

- (i) Fails to comply with any requirement of TSCA Title VI or this subpart;
- (ii) Makes any false or misleading statements on its application, records, or reports; or
- (iii) Makes substantial changes to personnel qualifications, procedures, or laboratories that make the TPC or TPC laboratory unable to comply with any applicable requirements of this subpart.

(2) *ABs.* EPA may suspend, revoke, or modify the recognition of an AB if the AB:

- (i) Fails to comply with the requirements of the applicable recognition agreement(s) (the International Accreditation Forum Multilateral Recognition

Arrangement and the International Laboratory Accreditation Cooperation Mutual Recognition Agreement or equivalent(s));

(ii) Fails to comply with any requirement of TSCA Title VI or this subpart;

(iii) Makes any false or misleading statements on its application, records, or reports; or

(iv) Makes substantial changes to personnel qualifications or procedures that make the TPC unable to comply with any applicable requirements of this subpart.

(3) *Process for suspending, revoking, or modifying accreditation or recognition.*

(i) Prior to taking action to suspend, revoke, or modify accreditation or recognition, EPA or the accreditation body will notify the recognized AB or the accredited TPC or TPC laboratory in writing of the following:

(A) The legal and factual basis for the proposed suspension, revocation, or modification.

(B) The anticipated commencement date and duration of the suspension, revocation, or modification.

(C) Actions, if any, which the affected AB or TPC or TPC laboratory may take to avoid suspension, revocation, or modification, or to receive accreditation in the future.

(D) The opportunity and method for requesting a hearing with EPA prior to final suspension, revocation, or modification.

(ii) If the affected AB or TPC or TPC laboratory requests a hearing in writing to EPA within 30 days of receipt of the notification, EPA will:

(A) Provide the affected accreditation body or TPC or TPC laboratory an opportunity to offer written statements in response to EPA's or the accreditation body's

assertions of the legal and factual basis for the proposed action.

(B) Appoint an impartial EPA official as Presiding Officer to conduct the hearing.

The Presiding Officer will:

(1) Conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing.

(2) Consider all relevant evidence, explanation, comment, and argument submitted.

(3) Notify the affected AB or TPC or TPC laboratory in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final EPA action which may be subject to judicial review. The order must contain the basis, commencement date, and duration of the suspension, revocation, or modification.

(iii) If EPA determines that the public health, interest, or welfare warrants immediate action to suspend the recognition of an AB or the accreditation of a TPC or TPC laboratory prior to the opportunity for a hearing, it will notify the affected AB, TPC, or TPC laboratory of its right to request a hearing on the immediate suspension within 15 days of the suspension taking place and the procedures for the conduct of such a hearing.

(iv) Any notification, decision, or order issued by EPA under this section, any transcript or other verbatim record of oral testimony, and any documents filed by a certified individual or firm in a hearing under this section will be available to the public, except as otherwise provided by TSCA section 14. Any such hearing at which oral testimony is presented will be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under TSCA section 14.

(v) EPA will maintain a publicly available list of accreditation bodies whose recognition has been suspended, revoked, modified, or reinstated and a publicly available list of TPCs and laboratories whose accreditation has been suspended, revoked, modified, or reinstated.

(vi) Unless the decision and order issued under this paragraph (d)(3) of this section specify otherwise, an AB whose recognition has been revoked or a TPC or TPC laboratory whose accreditation has been revoked must reapply for recognition or accreditation after the revocation ends in order to become recognized or accredited under this subpart again.

(vii) Unless the decision and order issued under paragraph (d)(3) of this section specifies otherwise, an AB whose recognition has been revoked or a TPC or TPC laboratory whose accreditation has been revoked, must immediately notify all TPCs or panel producers to which it provides TSCA Title VI accreditation or certification services of the revocation.

(f) *Process for denying a TSCA Title VI accreditation*--(1) Upon denying to accredit a TPC or a TPC laboratory for failure to submit a complete application, the accreditation body will notify the TPC or TPC laboratory in writing of the following:

- (i) The legal and factual basis for the denial.
- (ii) Actions, if any, which the affected TPC or TPC laboratory may take to receive accreditation in the future.
- (iii) The opportunity and method for requesting a hearing with EPA.

(2) If the affected TPC or TPC laboratory requests a hearing in writing to EPA within 30 days of receipt of the notice, EPA will:

(i) Provide the affected TPC or TPC laboratory an opportunity to offer written statements in response to the legal and factual basis for the denial.

(ii) Appoint an impartial EPA official as Presiding Officer to conduct the hearing. The Presiding Officer will:

(A) Conduct a fair, orderly, and impartial hearing within 90 days of the request for a hearing.

(B) Consider all relevant evidence, explanation, comment, and argument submitted.

(C) Notify the affected TPC or TPC laboratory in writing within 90 days of completion of the hearing of his or her decision and order. Such an order is a final agency action which may be subject to judicial review. The order must contain the basis for the denial.

(3) Any notification, decision, or order issued by EPA under this section, any transcript or other verbatim record of oral testimony, and any documents filed by a certified individual or firm in a hearing under this section will be available to the public, except as otherwise provided by TSCA section 14. Any such hearing at which oral testimony is presented will be open to the public, except that the Presiding Officer may exclude the public to the extent necessary to allow presentation of information which may be entitled to confidential treatment under TSCA section 14.

(g) *Process of seeking alternate accreditations or certifications*--(1) If AB is removed or withdraws from the TSCA Title VI Third-Party Certification Program:

(i) For reasons other than fraud or providing false or misleading statements, or other than a reason that implicates a particular TPC in a violation of TSCA Title VI or its

implementing regulations, TPCs accredited by that AB have 365 days, or 180 days if less than 365 days were left on their 3 year accreditation period, to be accredited again by an alternate EPA recognized AB.

(ii) Due to fraud or providing false or misleading statements with respect to a particular TPC, or for any other reason that implicates a particular TPC in a violation of TSCA Title VI or its implementing regulations, that TPC may not provide any TSCA Title VI certification services until it has been accredited by an alternate EPA recognized AB.

(2) If a TPC loses its accreditation or discontinues participation in the program:

(i) For reasons other than fraud or providing false or misleading statements, or other than a reason that implicates a particular panel producer in a violation of TSCA Title VI or its implementing regulations, the panel producers that used the TPC to certify their products must enlist another TPC to certify their products within 3 months (90 days). During the time a panel producer is seeking a new TPC, it must continue to comply with all other requirements of TSCA Title VI and its implementing regulations, including quality control testing.

(ii) Due to fraud or providing false or misleading statements with respect to a particular panel producer, or for any other reason that implicates a particular panel producer in a violation of TSCA Title VI or its implementing regulations, that panel producer may not offer regulated composite wood products for sale in the United States until its composite wood products have been recertified by another TPC.

§ 770.9 Prohibited Acts.

(a) Failure or refusal to comply with any requirement of TSCA section 601 (15 U.S.C. 2697) or this subpart part is a violation of TSCA section 15 (15 U.S.C. 2614).

(b) Failure or refusal to establish and maintain records or to make available or permit access to or copying of records, as required by this subpart, is a violation of TSCA section 15 (15 U.S.C. 2614).

(c) Violators may be subject to civil and criminal sanctions pursuant to TSCA section 16 (15 U.S.C. 2615) for each violation.

Subpart C--[Reserved]

Subpart D--Incorporation by Reference

§ 770.99 Incorporation by reference.

The materials listed in this section are incorporated by reference into this part with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, a document must be published in the **Federal Register** and the material must be available to the public. All approved materials are available for inspection at the OPPT Docket 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 legal 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. In addition, these materials are available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/

ibr_locations.html. These materials may also be obtained from the sources listed in this section.

(a) [Reserved]

(b) *ASTM material*. Copies of these materials may be obtained from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959, or by calling (877) 909-ASTM, or at <http://www.astm.org>.

(1) ASTM D6007-02 (Reapproved 2008) , October 1, 2008, Standard Test Method for Determining Formaldehyde Concentrations in Air from Wood Products Using a Small-Scale Chamber, IBR approved for § 770.7(a) through (c).

(2) ASTM D5582-00 (Reapproved 2006), October 1, 2006, Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator, IBR approved for § 770.7(a) through (c).

(3) ASTM E1333-10 (Approved May 1, 2010), Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber, IBR approved for § 770.7(a) through (c).

(c) *ISO material*. Copies of these materials may be obtained from the International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneve 20, Switzerland, or by calling +41-22-749-01-11, or at <http://www.iso.org>.

(1) ISO/IEC 17011:2004(E), Conformity Assessments--General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (First Edition) February 15, 2005, IBR approved for § 770.7(a) through (c).

(2) ISO/IEC 17020:1998(E), General Criteria for the Operation of Various Types of Bodies Performing Inspections (First Edition), November 15, 1998, IBR approved for

§ 770.7(a) through (c).

(3) ISO/IEC 17025:2005(E), General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for § 770.7(a) through (c).

(4) ISO/IEC Guide 65:1996(E), General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 770.7(a) through (c).

[FR Doc. 2013-13254 Filed 06/07/2013 at 8:45 am; Publication Date: 06/10/2013]