

Small Entity Compliance for Formaldehyde Standards in Composite Wood Products

Accreditation Bodies

National Program Chemicals Division
Office of Pollution Prevention and Toxics
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Background on TSCA Title VI

- On July 7, 2010, the Formaldehyde Standards for Composite Wood Products Act was signed into law to become Toxic Substances Control Act (TSCA) Title VI.
- TSCA Title VI establishes formaldehyde emission standards identical to the California Air Resources Board (CARB) limits.
- TSCA Title VI directs the implementation of regulations to ensure compliance with formaldehyde emission standards.
- The final rule is available in the Federal Register under 40 CFR Part 770 and posted online at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0461-0001>.
 - Became effective on May 22, 2017.
 - Beginning June 1, 2018, composite wood products (manufactured in or imported into the U.S.) must be certified as compliant with emission standards by a CARB approved and EPA-recognized Third-Party Certifier (TPC).**
 - Until March 22, 2019, regulated products must be labelled as compliant with the TSCA Title VI or CARB ATCM Phase II emission standards. After March 22, 2019, products must be labeled as TSCA Title VI compliant.**
 - Beginning March 22, 2019, import certification is required.*
 - Beginning March 22, 2024, non-exempt laminated products become hardwood plywood and must comply with panel producer requirements.*

* The final rule extending compliance dates is [available in the Federal Register online](#).

** On March 13, 2018, the U.S. District Court for the Northern District of California, issued an order addressing the litigation over the December 12, 2018 compliance date for the formaldehyde standards for composite wood products. [Read the Federal Register Notice announcing the litigation](#).

Regulation Summary

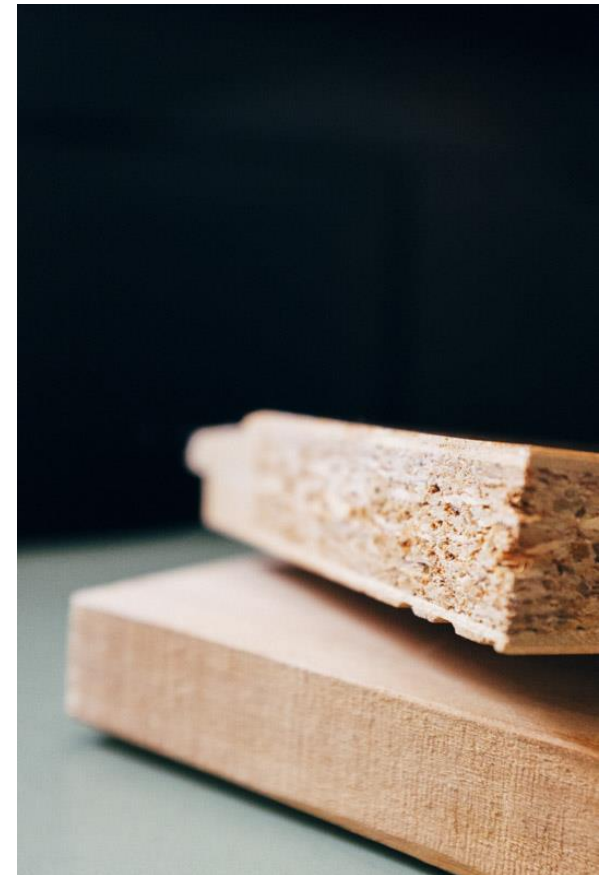
- TSCA Title VI requires that composite wood products be tested and certified, ensuring only compliant products enter the product supply chain.
- Composite wood products must be certified by an EPA-recognized third-party certifier (TPC), also called an EPA TSCA Title VI TPC.
- Composite wood products affected under TSCA Title VI are:
 1. Hardwood Plywood;
 2. Medium-Density Fiberboard (MDF), including thin MDF; and
 3. Particleboard.

* There are limited testing and certification exemptions for no-added formaldehyde (NAF) resins or ultra-low emitting formaldehyde (ULEF) resins.
- The new regulation includes recordkeeping, reporting, and labeling provisions.
- All applications and notifications submitted to EPA under the final rule must be done through the EPA Central Data Exchange (CDX) at: <https://cdx.epa.gov>.

Emissions Standards

Regulated products must meet the emission standards beginning June 1, 2018:

Product	Emission Standard
Hardwood Plywood – Veneer Core	0.05 ppm of formaldehyde
Hardwood Plywood – Composite Core	0.05 ppm of formaldehyde
Medium-Density Fiberboard	0.11 ppm of formaldehyde
Thin Medium-Density Fiberboard	0.13 ppm of formaldehyde
Particleboard	0.09 ppm of formaldehyde

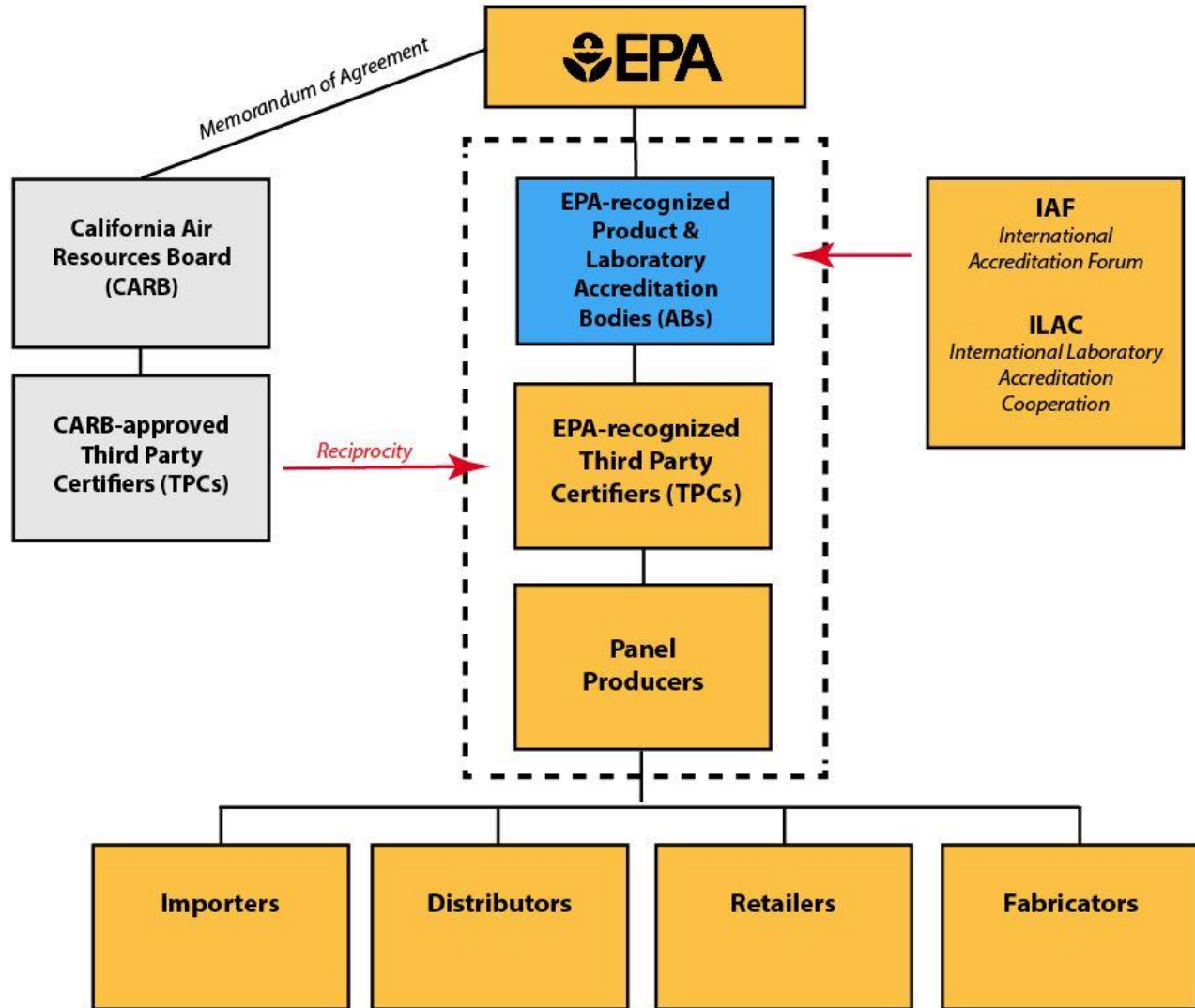




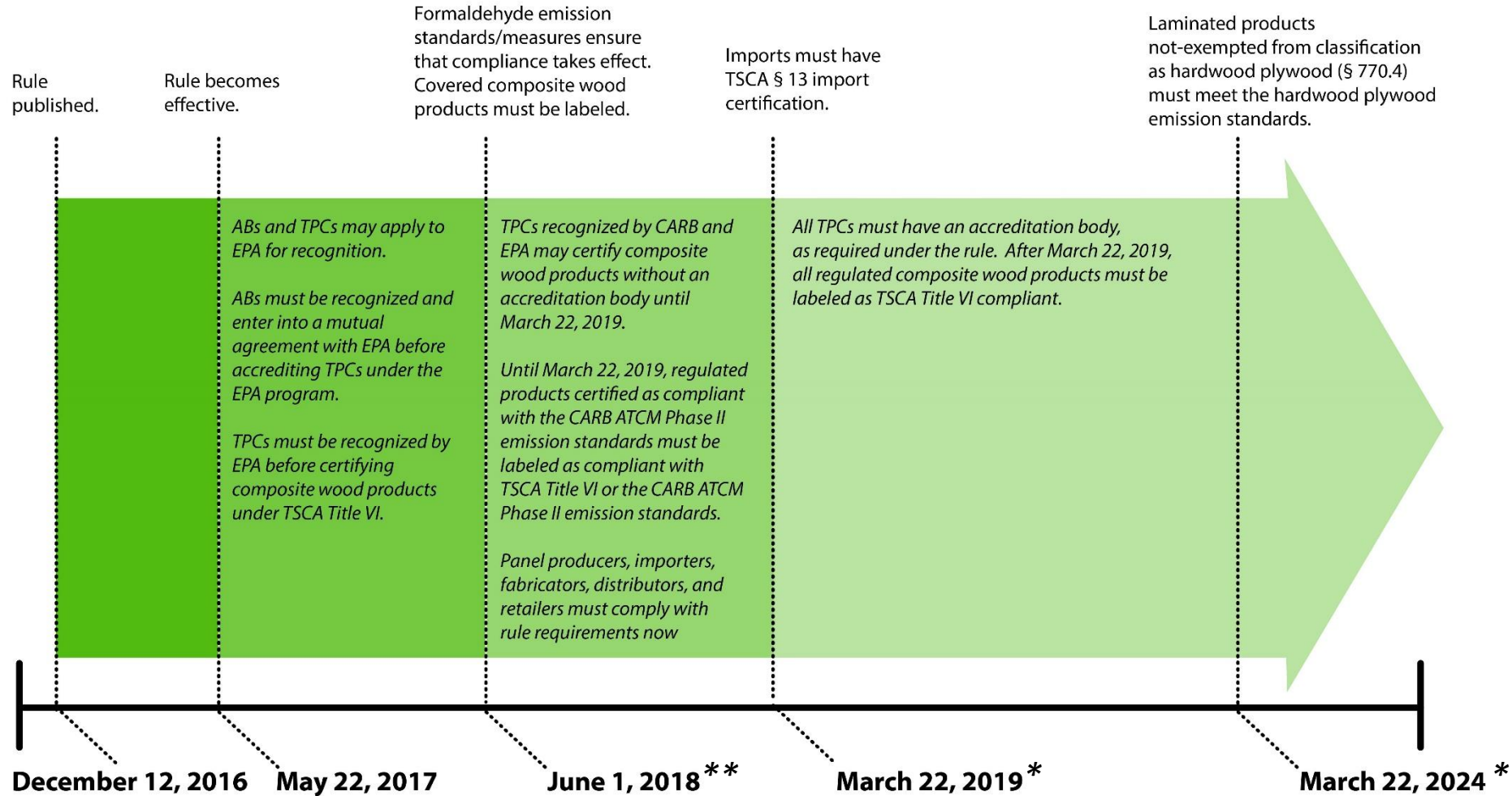
Rule Framework and Impacted Entities

Each entity must fulfill certain requirements to ensure that only compliant composite wood products enter the supply chain.

The dotted line represents the EPA's third-party certification program.

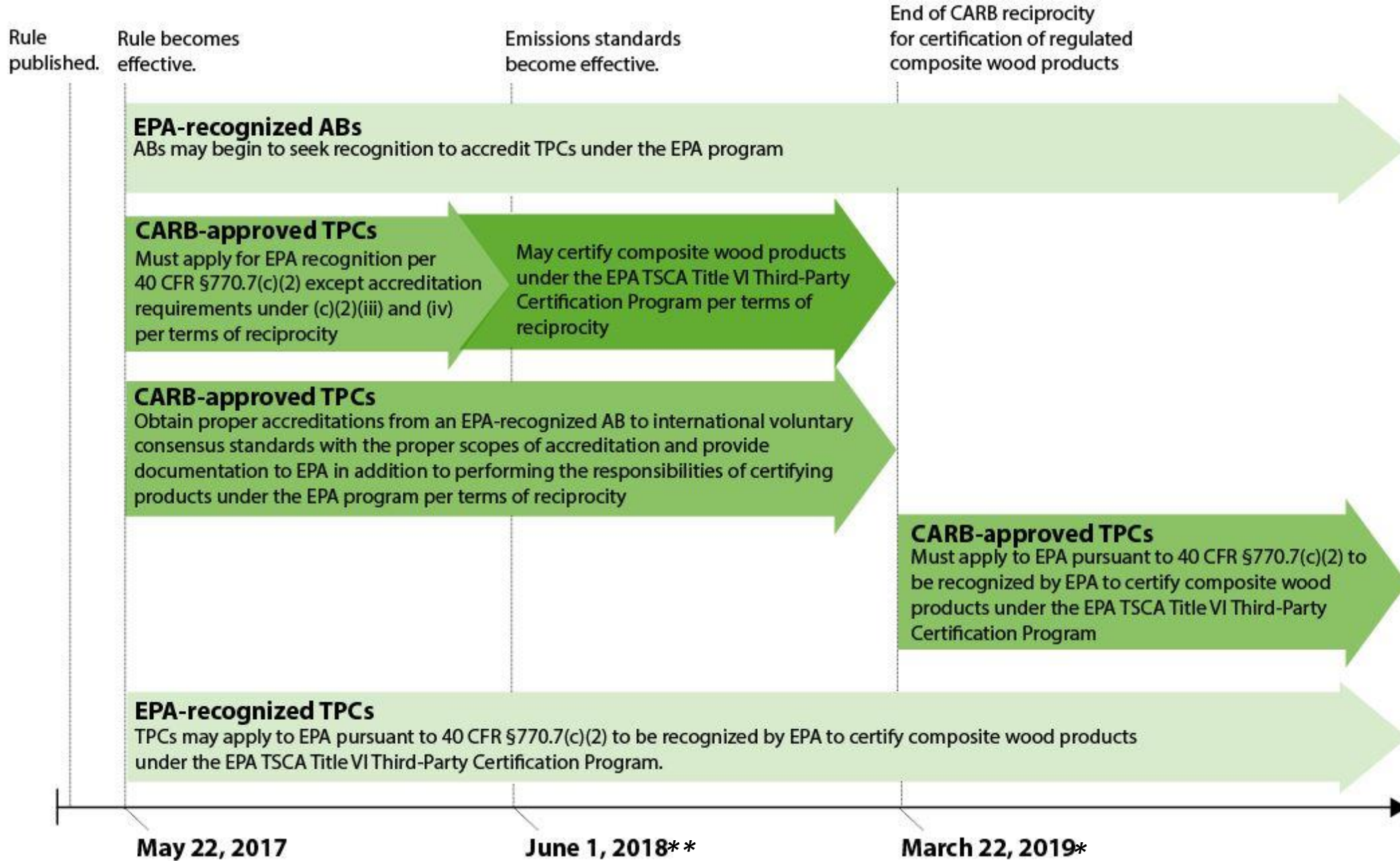


Compliance Timeline



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Becoming an EPA-Recognized Accreditation Body





Becoming an EPA-Recognized AB

There are three steps to become an EPA-Recognized Accreditation Body, also called an EPA TSCA Title VI AB:

1. Apply to the EPA program through EPA CDX



2. Enter a Recognition Agreement with EPA



3. Become an EPA TSCA Title VI Product or Laboratory AB

EPA recognizes that some ABs may be qualified to perform the roles of both types of ABs. Each of these steps includes specific compliance and application requirements, some of which are identical for both Product and Laboratory ABs.



Compliance Requirements

- In order for **Product ABs** to ensure TPCs are qualified to certify composite wood products, they must qualify for recognition by EPA.
- To qualify, applicants must be:
 1. A signatory to the International Accreditation Forum Inc.'s (IAF) Multilateral Recognition Arrangement (MLA) through level three, or have membership in one of the IAF recognized regional accreditation cooperations (or equivalent organization as determined by EPA);
 2. In conformance with the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17011:2004(E): General requirements for accreditation bodies accrediting conformity assessment bodies; and
 3. Competent to perform accreditation activities for product certification according to ISO/IEC 17065:2012(E): Requirements for bodies certifying products, processes and services.



Compliance Requirements

- In order for **Laboratory ABs** to ensure laboratories are qualified to conduct formaldehyde emissions laboratory testing services, they must qualify for recognition by EPA.
- To qualify, applicants must be:
 1. A signatory to the International Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), or have membership in one of the ILAC recognized regional accreditation cooperations (or equivalent organization as determined by EPA);
 2. In conformance with the ISO/IEC 17011:2004(E);
 3. Competent to ensure EPA-Recognized TPC inspection activities are in conformance with ISO/IEC 17020:2012(E): Requirements for the operation of various types of bodies performing inspection; and
 4. Competent to perform accreditation activities according to ISO/IEC 17025:2005(E): General Requirements for the competence of testing and calibration laboratories.



Compliance Requirements - Recognition by EPA

- Both Product ABs and Laboratory ABs (see 40 CFR §§770.7(a)(2) and (b)(2)) must submit applications to EPA.
- All candidate ABs must submit applications via CDX and obtain EPA recognition before accrediting TPCs under TSCA Title VI. EPA CDX registration guidelines can be found at: https://cdx.epa.gov/Content/Documents/CDX_Quick_User_Guide.pdf.
- For candidate ABs making a claim of Confidential Business Information (CBI):
 - Under TSCA §14(c)(3), companies are required to substantiate all CBI claims at the time of submission, except for a few categories of claims exempted from substantiation by TSCA §14(c)(2); and
 - Additionally, the 2016 TSCA now requires a supporting statement and certification for all confidentiality claims.
- Recognition agreements are required for both Product ABs (see 40 CFR §770.7(a)(3)) and Laboratory ABs (see 40 CFR §770.7(b)(3)).
- Each recognition agreement establishes a relationship between the AB and EPA to ensure the proper oversight of TPCs and is valid for three years; thereafter, renewal applications are required.

How to Comply





Your Responsibilities Under TSCA Title VI

1. You are responsible for ensuring TPCs and/or laboratories are properly accredited to the relevant ISO standards with a scope of accreditation that includes the TSCA Title VI regulatory standards. You must provide notifications to the EPA CDX for specific events pertaining to status change of TPCs or change to AB information.
2. You must maintain records and submit annual reports documenting TPC compliance with the requirements for assessment, reassessment, and surveillance on-site assessments.
3. Laboratory ABs must also verify participation in proficiency testing programs, if available.





Accreditation

- Product ABs must determine the accreditation eligibility and accredit each TPC seeking recognition under the EPA program by performing assessments.
- Assessments must include:
 - An on-site assessment to determine whether the TPC meets the requirements of ISO/IEC 17065:2012(E);
 - A checklist developed and used by the Product AB of TPC requirements under 40 CFR section 770.7 and key accreditation elements of ISO/IEC 17065:2012(E); and
 - A review of how the TPC:
 - Verifies formaldehyde emissions tests;
 - Verifies formaldehyde quality control tests;
 - Evaluates the panel producer's quality assurance and quality control processes/personnel/manual;
 - Reviews the accreditation credentials of the TPC laboratory;
 - Evaluates the approach used for establishing correlation between ASTM E1333-14 and ASTM D6007-14, if used, or other allowable test method under 40 CFR section 770.20(b); and
 - Evaluates the process for sample selection, handling, and shipping procedures for panel producer quality control testing.

Accreditation

- Laboratory ABs must determine the accreditation eligibility and accredit each TPC seeking recognition under the EPA program by performing assessments.
- Assessments must include:
 - An on-site assessment to determine whether the laboratory meets the requirements of ISO/IEC 17025:2015(E) and TPC requirements under 40 CFR §770; and
 - A checklist developed and used by the Laboratory AB of TPC requirements under 40 CFR section 770.7(c)(4) and key accreditation elements of ISO/IEC 17025:2005(E).
- In accordance with ISO/IEC 17011:2004(E) Section 7.11, all ABs must conduct a follow-up reassessment or surveillance on-site assessment of each TPC laboratory that the AB has accredited.



Notifications

- Each Product AB (see 40 CFR §770.7(a)(5)(iv)) and Laboratory AB (see 40 CFR §770.7(b)(5)(v)) must provide the following notifications to the EPA CDX for the following events:
 - Loss of status as a signatory to the IAF MLA or ILAC MRA, or loss of membership in one of the recognized regional accreditation cooperations;
 - When TPCs fail to comply with any provision of 40 CFR part 770;
 - Where there is a suspension, reduction, or withdrawal of an EPA-recognized TPC or TPC laboratory; and
 - Where there is a change in a non-domestic AB's agent for service.



Records and Annual Reports

- *Records:* Each AB must electronically maintain checklists and other records documenting compliance with the requirements for assessment, reassessment, and surveillance on-site assessments of EPA-recognized TPCs and TPC laboratories for three years.
- *Annual Reports:* ABs must provide EPA an annual report electronically via EPA CDX on or before March 1st of each year for the AB services performed during the previous calendar year.
 - This should include the number and locations of assessment, reassessment, and surveillance on-site assessments performed for each EPA-recognized TPC or TPC laboratory.



Impartiality and Proficiency

- Impartiality-40 CFR §770.7(a)(4) & (b)(4): Both Product and Laboratory ABs must commit to act impartially when performing activities under the EPA program.
 - This commitment is consistent with the impartiality provisions of ISO/IEC standards incorporated into the final rule.
- Proficiency-40 CFR §770.7(b)(5)(iii): Laboratory ABs must verify that TPC laboratories participate in the CARB inter-laboratory comparison for formaldehyde emissions testing to help ensure TPC laboratory proficiency in formaldehyde emissions testing.
 - In lieu of CARB's inter-laboratory comparison, ABs must ensure that the TPC laboratory participates in an EPA-recognized proficiency testing program if available.
- EPA meetings-40 CFR §770.7(a)(5)(vii) & (b)(5)(viii): Both Product and Laboratory ABs must meet with EPA at least once every two years in person, via teleconference, or through other virtual methods to discuss the implementation of the EPA program.
- Inspections-40 CFR §770.7(a)(5)(viii) & (b)(5)(ix): Both Product and Laboratory ABs must allow EPA to inspect their facilities upon the presentation of appropriate credentials and written notification.



Suspensions, Revocations, Denials

- EPA reserves the right to suspend, revoke or modify the recognition of an AB.
- EPA will notify the AB in writing if a request for recognition is denied.
- If an AB loses its recognition or withdraws, TPCs accredited by that AB can continue to certify products under TSCA Title VI for 180 calendar days, after which the TPC must be accredited by another EPA-recognized AB and re-recognized by EPA.
 - If the particular TPC is implicated in a violation, the TPC may not provide any TSCA Title VI certification services until it has been accredited by another EPA-recognized AB and re-recognized by EPA.



Transitional Period

- There is a transitional period (until March 22, 2019) for all CARB-approved TPCs to comply with TSCA Title VI, during which time they can certify products without meeting TSCA Title VI accreditation requirements. However, CARB TPCs must apply to EPA CDX and be recognized under the EPA program before certifying composite wood products under TSCA Title VI.
- Before the end of the transitional period on March 22, 2019, all CARB-approved TPCs must be accredited by EPA TSCA Title VI AB(s) and have applied to EPA CDX with documentation of those accreditation credentials to continue to certify products.
- EPA will approve TPC applications directly and will recognize qualifying CARB-approved TPCs that apply under the EPA TSCA Title VI Third-Party Certification Program through the terms of the EPA/CARB memorandum of agreement.

For More Information



Contact your EPA regional office for specific local requirements.



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Visit EPA's website for updates: <http://www.epa.gov/formaldehyde>.

