announcing the withdrawal of two proposed rules that published in the Federal Register. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because these proposed rules need to be reconsidered based on public comments received and new information developed after the publication of the proposed rules.

DATES: As of November 1, 2018, the proposed rules published on June 24, 2013, at 78 FR 37723, and October 17, 2016, at 81 FR 71415 are withdrawn.

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5318, Silver Spring, MD 20993–0002, 301–796–5837, Madhusoodana.Nambiar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Agency’s regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or should be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

<table>
<thead>
<tr>
<th>Title of proposed rule</th>
<th>Publication date, Federal Register citation</th>
<th>Docket No.</th>
<th>Reason for withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Laser Products: Proposed Amendment to Performance Standard.</td>
<td>June 24, 2013, 78 FR 37723.</td>
<td>FDA–2011–N–0070</td>
<td>The proposed rule referenced an international performance standard. That international standard is now being revised to reflect advancements in technology. FDA wants to have the most current international standard as a reference before publishing a final rule on laser products.</td>
</tr>
<tr>
<td>2. Electronic Submission of Labeling for Certain Home-Use Medical Devices.</td>
<td>October 17, 2016, 81 FR 71415.</td>
<td>FDA–2016–N–2491</td>
<td>Several adverse comments challenged the proposed FDA-managed labeling database as being unduly burdensome on both FDA and on industry, without efficiently enhancing public health. Additionally, concerns regarding the proposed format and potential costs for industry to fully implement were also raised. Based on the adverse comments, this rule-making would benefit from being withdrawn at this time and reconsidered. The Agency plans to reconsider its approach and solicit further public input at a future date.</td>
</tr>
</tbody>
</table>

The withdrawal of these proposals identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposals listed in the chart. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment.

Furthermore, this withdrawal of the proposed rules is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rules, you may review the Agency’s website (https://www.fda.gov) for any current information on the matter.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–23916 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 770
[64 FR 5984–14]

RIN 2070–AK47

Technical Issues—Formaldehyde Emission Standards for Composite Wood Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the regulations promulgated in a final rule that published in the Federal Register on December 12, 2016, concerning formaldehyde emission standards for composite wood products. EPA is publishing these proposed amendments to address certain technical issues and to further align the final rule requirements with the California Air Resources Board (CARB) Airborne Toxic Control Measures (ATCM) Phase II program. Addressing these technical issues would add clarity for regulated entities. These revisions to the existing rule would also streamline compliance programs and help to ensure continued smooth transitions for supply chains to comply with the requirements associated with regulated composite wood products.

DATES: Comments must be received on or before December 3, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0174, by one of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.


• Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please...
follow the instructions at http://www.epa.gov/dockets/contacts.html. Additional instructions on commenting or visiting the docket, along with more information about docket generally, is available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:
For technical information contact: Todd Coleman, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–564–1208; email address: coleman.todd@epa.gov.
For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:
I. General Information
A. Does this action apply to me?
You may be affected by this proposed rule if you manufacture (including import), sell, supply, offer for sale, test, or work with the certification of hardwood plywood, medium-density fiberboard, particleboard, and/or products containing these composite wood materials in the United States. The following list of North American Industry Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Veneer, plywood, and engineered wood product manufacturing (NAICS code 3212).
- Manufactured home (mobile home) manufacturing (NAICS code 321991).
- Prefabricated wood building manufacturing (NAICS code 321992).
- Furniture and related product manufacturing (NAICS code 337).
- Furniture merchant wholesalers (NAICS code 42321).
- Lumber, plywood, millwork, and wood panel merchant wholesalers (NAICS code 42331).
- Other construction material merchant wholesalers (NAICS code 423390), e.g., merchant wholesale distributors of manufactured homes (i.e., mobile homes) and/or prefabricated buildings.
- Furniture stores (NAICS code 4441).
- Building material and supplies dealers (NAICS code 4441).
- Manufactured (mobile) home dealers (NAICS code 4539).
- Motor home manufacturing (NAICS code 336213).
- Travel trailer and camper manufacturing (NAICS code 336214).
- Recreational vehicle (RV) dealers (NAICS code 441210).
- Recreational vehicle merchant wholesalers (NAICS code 423110).
- 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).

If you have any questions regarding the applicability of this action, please 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 preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

II. Background
A. Comments Received on Technical Issues
1. Stakeholder Feedback. Since the formaldehyde emission standards for composite wood products final rule (see 82 FR 31922), extending the compliance dates in the December 12, 2016 final rule (see 82 FR 44533 and 83 FR 14375), and updating several voluntary consensus standard versions as well as the equivalence provisions between the American Society for Testing and Materials (ASTM) E1333–14 and ASTM D6007–14 test chambers (see 82 FR 5340).

2. June 28, 2018 Public Meeting on the Technical Issues. On May 24, 2018, the Agency published a notice in the Federal Register (see 83 FR 24104) announcing a public meeting at the EPA headquarters office in Washington, DC (with remote access available) on June 28, 2018 to discuss and obtain input on the technical issues that stakeholders have raised since the December 12, 2016 final rule. The publication of this notice also opened a 60-day public comment period to allow the public time to submit any additional data, information, or comments for the Agency to consider in developing this proposal.

During the June 28, 2018 public meeting, the Agency presented 11 technical issues and provided registered attendees the opportunity to comment on each issue and raise any additional issues before the conclusion of the meeting that had not been discussed. A transcript of this public meeting, letters, correspondence, and background materials are also posted in the Supporting Documents section of the docket for this action.

The Agency received 8 comments during the 60-day comment period opened for the public meeting. Those comments, in addition to the attendee feedback during the June 28, 2018 public meeting and the previously submitted letters and correspondence following the December 12, 2016 final
rule, have resulted in the identification of technical issues that the Agency is considering and, in most cases, addressing, by proposing to amend the TSCA Title VI regulations in this proposed rule.

Because the Agency has already taken public comment for 60 days on the majority of technical issues after the Federal Register notice announcing the public meeting (see 83 FR 24104) and given that the commenters were generally supportive of these changes, the comment period for this proposed action will be 30 days. Furthermore, the Agency is considering the use of an immediate or 15-day effective date upon publication of the final rule to provide regulated stakeholders time to adjust their certification programs before, or as close as possible to the March 22, 2019 TSCA Title VI rule’s CARB reciprocity end date (see 83 FR 14375). Certain of the technical issues being proposed in this action would further align the TSCA Title VI program with the CARB ATCM Phase II program and streamline compliance with those entities currently certifying under CARB’s program.

Stakeholders have noted that having the effective date for these amendments at or before the March 22, 2019 TSCA Title VI rule’s CARB Reciprocity end date will ensure TPC program consistency and provide regulatory certainty as those programs can continue to operate as they have for years under the CARB ATCM Phase II program.

B. What action is the Agency taking?

a. Experimental resins and mill startup and restart scenarios. The Agency is aware that the final rule does not directly discuss provisions for composite wood product mills that are starting up new operations, or mills that are restarting operations after a cessation in production, which would require working with a TSCA Title VI TPC to establish new correlations for producing what was a previously certified product. Stakeholders asked about this issue and requested the Agency provide guidance on it in addition to guidance on a path for products transitioning from research and development to regulated composite wood products.

On June 1, 2018, to address these two issues, the EPA posted guidance in the form of frequently asked questions on the Agency’s formaldehyde homepage (Ref 1). In these frequently asked questions, the Agency outlined an example approach that could lead to prompt certification of composite wood products for start-up or restarting mills and products transitioning from research and development to be certified under the existing testing and certification provisions of the rule. The Agency received comments from a few stakeholders (see EPA–HQ–OPPT–2018–0174–0018, EPA–HQ–OPPT–2018–0174–0020, and EPA–HQ–OPPT–2018–0174–0022) requesting the Agency to provide more example approaches in the frequently asked questions. Stakeholders noted that there are other scenarios that could be used which are not directly identified in the existing frequently asked questions. EPA understands the issue and notes that the example approach used in the existing frequently asked questions is just one of many possible approaches which would be permitted under the TSCA Title VI regulations. So long as the TSCA Title VI TPC and panel producer are establishing a certification program that complies with the TSCA Title VI regulations, any such “example” or “optional” approach could be used. It is the Agency’s understanding that there could be numerous mill start up and restart scenarios, which would be a challenge to accurately capture and develop rule provisions for without being inadvertently limiting in some way. The Agency believes the existing rule provisions and guidance it has already provided in the frequently asked questions are adequate and flexible enough to allow mills and TSCA Title VI TPCs to use their expertise and work together to develop timely approaches that are tailored to their specific scenarios and that ensure the manufacture of composite wood products which are compliant with the rule. Accordingly, EPA is not proposing new rule provisions for mill start-up and restarts, or the use of new or otherwise experimental resins.

b. Annual correlations between the third-party certifier ASTM E1333 or equivalent ASTM D6007 apparatus and any other mill quality control testing method. EPA is proposing to amend the rule by removing the requirement for annual correlations at § 770.20(d). The rule currently requires a showing of correlation between the TSCA Title VI TPC’s ASTM E1333–14 apparatus (or contract laboratory’s ASTM E1333–14 apparatus) and any other mill quality control testing methods at § 770.20(b) on an annual basis for the first three years after initial correlation establishment, and every two years thereafter to continue certifying composite wood products. The CARB ATCM Phase II program does not require annual correlations between the TPC (or contract laboratory) ASTM E1333–14 apparatus or equivalent ASTM D6007–14 apparatus and any other approved method for quality control testing. The CARB ATCM Phase II program requires that an initial correlation be established between the ASTM E1333–14 apparatus (or contract laboratory’s ASTM E1333–14 apparatus) or equivalent ASTM D6007–14 apparatus and any other approved method for quality control testing, and then be reestablished only when there is a significant change in the operation at the mill or when there is a reason to believe the correlation is no longer valid. Stakeholders have requested that EPA amend § 770.20(d) to align with the CARB ATCM Phase II correlation requirement. CARB’s ATCM requires panel producers to work with a TPC to develop an initial correlation. CARB staff have noted that requiring subsequent correlations only on an as-needed basis (rather than requiring that a correlation be redeveloped annually) has not reduced the quality of testing data or composite wood products meeting the emission standard under the CARB ATCM Phase II program.

CARB staff have also noted that should there be any issue with the validity of the correlation, the panel producer and TPC would notice immediately as the results from quarterly and quality control testing would vary considerably from what would be expected for any given product type being tested. Stakeholders as well have expressed that the removal of the annual correlation requirement would result in a streamlined path to compliance while having no negative affect on the validity of the test data received from either the TSCA Title VI TPC’s testing apparatus nor the mill quality control testing method at § 770.20(b).

c. Equivalence or correlation on like-size or similar sized apparatuses. EPA is proposing an amendment to § 770.20(d) to allow the TSCA Title VI TPC to use their ASTM E1333–14 apparatus (or their contract laboratory’s ASTM E1333–14 apparatus) to demonstrate equivalence to multiple ASTM D6007–14 apparatuses of a similar model or size and construction located in the same TSCA Title VI TPC laboratory, or contract laboratory. Similar model chambers would be those that are manufactured by the same manufacturer and bear the same model number or bear a model number that succeeds a previous model number that has been discontinued or otherwise is no longer being manufactured but would be deemed the equivalent by the manufacturer. Similar size and construction chambers would have an identical chamber volume capacity and be constructed in a way that would
result in the same sample holding capacity and operational parameters (e.g., airflow speed, time to conduct testing, etc.) as another chamber, but need not be made by the same manufacturer. The Agency understands that CARB has allowed a similar approach under the ATCM Phase II program and there has been no negative impact on generation of data to demonstrate valid equivalence between test methods.

EPA is also proposing to update the correlation requirement at § 770.20(d) to allow multiple similar model or size and construction mill quality control test method apparatuses located at any one physical mill quality control testing laboratory to demonstrate correlation to the TSCA Title VI TPC test apparatus as required under § 770.20(d) in the same capacity as the amended equivalence allowance. Although not currently discussed in the CARB ATCM Phase II program, stakeholders note that some mills have multiple quality control testing apparatuses of the same or like model at each mill location, and being able to establish correlations to like model or size and construction apparatuses located at any one physical mill location would streamline compliance while having no impact on data quality and quality control testing. EPA is proposing to codify this interpretation of the TSCA Title VI regulation.

d. Averaging of emission test results during quarterly and non-complying lot testing. EPA is proposing to add subparagraph (iv) to § 770.20(c)(2) and amend subparagraph (i) at § 770.22(c)(2) to align with the CARB ATCM Phase II program regarding averaging test results during quarterly testing and non-complying lot retesting. CARB’s approved method for test results averaging accounts for formaldehyde emission variability across any one composite wood product panel while ensuring the products still meet the applicable emission standards. CARB’s method at 17 California Code of Regulations section 93120.9(a)(2)(A) and (B)(2) and Appendix 2 (g)(8) of its regulations includes allowing nine subsamples from any one panel to be collected and tested in an ASTM E1333-14 or equivalent ASTM D6007–14 apparatus in groups of three, resulting in three test values, which are then averaged to obtain one final value that accounts for emission variability across that one panel (Ref 2). Under these requirements, the nine subsamples should be randomly distributed and represent similar sizes to one another as they are collected from any one panel.

CARB does not address the averaging of test results for quality control testing in the ATCM program. EPA is not proposing an update to the quality control testing requirements; rather EPA is proposing to explicitly allow averaging of data generated for quarterly testing and non-complying lot retesting. EPA believes that this added clarity will assist TSCA Title VI TPCs and panel producers in testing composite wood products in the same capacity that they have been testing under the CARB ATCM, and that this amendment will not reduce test data quality.

e. Equivalence testing emission ranges. EPA is proposing to update the requirement at § 770.20(d) for TSCA Title VI TPCs to demonstrate equivalence under specified emission ranges. The CARB ATCM specifies that ten comparison tests must be conducted, consisting of at least five comparison tests in two of three specified emission ranges. CARB’s ATCM at 17 California Code of Regulations section 93120.9(a)(2)(B)(3) specifies the three emission ranges as (1) low—for products demonstrating formaldehyde emissions of less than 0.07 parts per million (ppm); (2) intermediate—for products demonstrating formaldehyde emissions from 0.07 ppm to less than 0.15 ppm; and (3) upper—for products demonstrating formaldehyde emissions from 0.15 ppm to 0.25 ppm (Ref 2). The current TSCA Title VI regulation does not require demonstration of equivalence across separate emission ranges as the CARB ATCM Phase II program does; rather, the TSCA Title VI regulation requires that a minimum of five comparison sets are required to represent the range of product emissions a TPC expects to certify. EPA is proposing to align with CARB’S ATCM and their requirement for ten comparison tests, consisting of five comparison tests in two of the three specified ranges (with a modification to the emission ranges and a modification to the requirement for demonstration across two ranges based on comments submitted by CARB) (see EPA—HQ—OPPT—2018–0174–0022). First, in the proposed emission ranges for the equivalence comparison tests under the TSCA Title VI regulation, EPA proposes to modify the values for the emission ranges from the current guidance under the CARB ATCM Phase II program. EPA understands that CARB intends to update their low emission range by changing the value to formaldehyde emissions of less than or equal to 0.05 ppm, which would change the intermediate range as well. This emission range corresponds to the emission standard for hardwood plywood. EPA is aware of several TPCs who only certify hardwood plywood and would prefer only demonstrating equivalence in this range. EPA agrees that the low range should be reserved for products that demonstrate formaldehyde emissions of less than or equal to 0.05 ppm and this will require a corresponding adjustment to the intermediate range, which would begin with the value of formaldehyde emissions greater than 0.05 ppm instead of the current 0.07 ppm and cover those products with emission up to 0.15 ppm. The upper emission range would remain the same for TSCA Title VI TPCs and mills that choose to demonstrate equivalence of their apparatuses at this upper range.

The second modification EPA is proposing in the TSCA Title VI regulation regarding testing emission ranges, which is a deviation from the current guidance under the CARB ATCM Phase II program, involves the requirement for demonstration of equivalence across two ranges if the TSCA Title VI TPC will only certify composite wood products in either the low or intermediate range, but not both. Regulated composite wood products emitting formaldehyde at a value meeting the upper emission range would not be compliant with the emission standards under the TSCA Title VI regulation. EPA is proposing that those TSCA Title VI TPCs who will only certify in one range may demonstrate equivalence for that range only, using at least five comparison tests to demonstrate equivalence in that range. TPCs certifying in two ranges would be required to conduct at least five comparison tests in each range—for a minimum number of ten comparison tests. The TSCA Title VI TPC would be restricted to only certifying product in this emission range if they choose to only demonstrate equivalence in one range (i.e., low, intermediate, or upper according to § 770.20(d)(1)(iv)(A) through (C)); EPA is proposing to codify this in the TSCA Title VI regulation.

f. Determination of equivalence only if mill uses TSCA Title VI TPC for all testing. EPA is proposing to amend § 770.20(d) to clarify that mills that do not perform any testing on-site at the mill and instead use their TSCA Title VI TPC for all quarterly and quality control testing would not be required to establish correlation as they are already using a TSCA Title VI TPC according to the ATCM Phase II program, and mills that choose to demonstrate equivalence have noted that when a panel producer uses the TSCA Title VI TPC for all
testing under the TSCA Title VI regulation, they are using either an ASTM E1333–14 or equivalent ASTM D6007–14 testing apparatus which as the rule is currently written could lead one to interpret that the test chamber must be correlated to itself. The EPA’s posted guidance on this issue in the form of a frequently asked question on the Agency’s formaldehyde homepage noted that the ASTM D6007–14 test apparatus that shows equivalence to the TSCA Title VI TPCs ASTM E1333–14 test apparatus according to § 770.20(d) would necessarily show correlation to itself under § 770.20(d)(2) and could be used as a quality control test method without additional correlation testing (Ref 1). EPA is proposing to codify this interpretation of the TSCA Title VI regulation.

g. Correlation coefficients and ‘r’ values. EPA is proposing to amend § 770.20(d)(2) to expand the options for TSCA Title VI TPCs and mills in establishing correlation coefficients and ‘r’ values beyond the linear regression model currently required by the TSCA Title VI regulations, in order to include the CARB ATCM Phase II approved cluster approach (also known as the point of origin approach in practice) and threshold approach. CARB’s alternative correlation coefficient and ‘r’ value method guidance document (CWP–10–001 [June 8, 2010]) outlines these two additional approaches for how TPCs certifying composite wood products under the CARB ATCM Phase II program may show correlation (Ref 3). EPA is proposing the addition of rule provisions for the “cluster approach” and “threshold approach” in § 770.20(d)(2)(i) and updating the requirement for certification at § 770.15(c)(1)(vii) and § 770.15(c)(2)(v). The addition of these approaches will aid TSCA Title VI TPCs in meeting the correlation requirements for manufacturers producing low formaldehyde-emitting products. Although the cluster approach uses the same linear regression line and ‘r’ values listed at § 770.20(d)(2)(i), the threshold approach does not. The threshold approach creates a “do not exceed limit” for composite wood products which provides a margin of safety relative to the maximum value of the data point clusters which are achieved through the use of the existing linear regression testing or the cluster approach.

h. Notifications of exceedance of quality control limit (QCL). EPA is proposing an amendment at § 770.7(c)(4)(v)(c) to clarify that notification of a non-complying lot through the EPA’s Central Data Exchange system by a TSCA Title VI TPC will be required within 72 hours of the time when the TSCA Title VI TPC is notified of the third QCL exceedance by a panel producer. EPA views this as a minor editorial clarification that would amend the rule text such that the requirement reads the way EPA had originally intended.

i. No-added formaldehyde (NAF)-based resin and ultra-low-emitting formaldehyde (ULEF) resin testing requirements. EPA is proposing the amendment of the NAF and ULEF testing requirements to align with the CARB ATCM Phase II program. The TSCA Title VI final rule requires that under the NAF requirements at § 770.17 a minimum of five tests be conducted pursuant to the NAF two-year exemption application while CARB’s TPC Bulletin 1 notes that 13 tests are the minimum permitted for a limited exemption (Ref 4). Additionally, the TSCA Title VI final rule requires that under the ULEF requirements at § 770.18, a minimum of ten tests be conducted pursuant to the ULEF two-year exemption or reduced testing application while CARB’s TPC Bulletin 1 notes that 26 tests are the minimum permitted for a limited exemption (Ref 4). Stakeholders note that although EPA will accept existing CARB executive orders for NAF and ULEF products from panel producers in good standing as outlined in § 770.17(d) and § 770.18(e), the two programs are not equal in the number of samples required, and the CARB ATCM Phase II program requires more samples. To promote regulatory consistency between the two programs, the EPA is proposing to adopt the CARB-required 13 tests for NAF and 26 tests for ULEF applications under the TSCA Title VI NAF two-year exemption application and ULEF two-year exemption or reduced testing application. The Agency does not believe this amendment will alter any in significant way how TSCA Title VI TPCs and panel producers currently conduct testing under the CARB ATCM Phase II or TSCA Title VI program, as EPA allows the use of equal or more stringent testing approaches (i.e., more tests) and it is EPA’s understanding that TSCA Title VI TPCs have continued to conduct testing the same way they have done for years under the CARB ATCM Phase II program.

j. Voluntary Consensus Standards incorporated by reference at § 770.99. EPA is proposing to update the references for two International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) voluntary consensus standards that were incorporated by reference in the December 12, 2016 final rule. Although these standards have been updated since the December 12, 2016 final rule was published, they were updated after the Agency proposed to update other voluntary consensus standards in an October 25, 2017 notice of proposed rulemaking (see 82 FR 49302). Table 1 in this Unit outlines the voluntary consensus standards that would be updated in this proposal and the respective updated versions. All other standards in the formaldehyde emission standards for composite wood products regulations will continue to be incorporated by reference as they appear in the existing regulation.

<table>
<thead>
<tr>
<th>Table 1—Voluntary Consensus Standards Comparison</th>
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<tbody>
<tr>
<td><strong>Current standard established by final rule (81 FR 89674)</strong></td>
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</tbody>
</table>

EPA proposes to adopt the updated versions of the standards referenced in Table 1. Specifically, EPA proposes to revise the current references to sections 7.5 to 7.11 of the 2004 version of ISO/IEC 17011 to the corresponding sections 7.4 to 7.13 of the 2017 version. As well, EPA proposes to revise the current reference to section 7.11 of the 2004
version of ISO/IEC 17011 to the corresponding section 7.9 of the 2017 version. EPA also understands that stakeholders prefer to use the current versions of the standards in both regulatory and non-regulatory programs stakeholders are involved with in their capacity as accreditation bodies or TPCs. Any future versions or updates to withdrawn/superseded standards will be announced by EPA through a separate Federal Register document with opportunity for public comment.

k. Clarification in the non-complying lot provisions. Stakeholders requested clarity on the intent of the non-complying lot provisions at §770.22 and how those provisions might apply to fabricators, importers, retailers or distributors who are notified by panel producers that a composite wood product they were supplied is found to be non-compliant after those composite wood products have been further fabricated into component parts or finished goods. The Agency previously posted guidance on this issue in the form of frequently asked questions on the Agency's formaldehyde homepage.

The guidance outlines the requirements for all entities in the supply chain and makes clear that, if the panel is still in panel form, the entity in possession of the non-compliant panel is to work with the panel producer to isolate, treat, and restest the panels, as needed. If the panels from the non-complying lot have been incorporated into component parts or finished goods, the remainder of §770.22 does not apply beyond when those panels were fabricated into the component parts or finished goods (Ref 5).

EPA notes that the regulatory intent behind the non-complying lot provisions at §770.22 was to manage those non-compliant composite wood products in their panel form and not after those panels have been fabricated into component parts or finished goods. EPA understands that it would be a significant tracking burden for fabricators to determine exactly which component parts or finished goods those panels may have been fabricated into, and, therefore, impractical from a chain of custody management approach. As such, the Agency proposes to include the clarifying guidance in §770.22 to make clear the initial regulatory intent of the December 12, 2016 final rule and promote regulatory certainty.

1. Labels on regulated composite wood products and finished goods containing composite wood products at point of manufacture, fabrication, and/or import. EPA is proposing to clarify in §770.45 that regulated composite wood products and finished goods containing composite wood products must be labeled at the point of manufacture or fabrication, and if imported, the label must be affixed to the product as a condition of entry into the port. Under TSCA, the term “manufacture” includes import, meaning that regulated composite wood products or finished goods containing such products imported into the customs territory of the U.S. must be accompanied at the time of import by a label as required by §770.45 and this proposed amendment would just clarify this requirement. It is the Agency’s understanding that industry currently interprets and implements the §770.45 labeling provision as EPA originally intended (and is now proposing to clarify).

m. Labels on panels manufactured under NAF limited exemption at §770.17 and ULEF limited exemption at §770.18. EPA is proposing to clarify that panels manufactured under a limited exemption at §770.17 and §770.18 from certain final rule requirements or existing CARB executive orders for NAF and ULEF products from panel producers in good standing as outlined in §770.17(d) and §770.18(e) may be labeled as TSCA Title VI “compliant” and need not read “certified.” EPA understands that the regulatory language at §770.45(a) requires the use of the term “certified” on composite wood products. For the purposes of panels made under a limited exemption at §770.17 and §770.18 or existing CARB executive orders, however, the use of the term “compliant” should be allowed as those panels have demonstrated they meet the emission standards and the exemption requirement; however, they are not “certified” in the same capacity that other composite wood products are due to the existing, limited exclusion from certification requirements under §770.15 and §770.40(b).

n. TSCA Title VI manufactured-by date. In the final rule, EPA also intends to conform the manufactured-by date in the Code of Federal Regulations to correspond to the manufactured-by date of June 1, 2018 resulting from the court order announced by EPA in a Federal Register notice on April 4, 2018 (see 83 FR 14375). Specifically, EPA is proposing to replace December 12, 2016 final rule and make clear the initial regulatory intent of the December 12, 2016 final rule and promote regulatory certainty.

B. What is the Agency’s authority for taking this action?

These regulations are established under authority of section 601 of TSCA, 15 U.S.C. 2697.

III. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, in addition to the 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.


IV. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563.
B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 et seq., because it does not create any new reporting or recordkeeping obligations. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2070–0185.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 et seq. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As addressed in Unit II.A., this action would not significantly alter the TSCA Title VI regulations or supporting economic analysis for the December 12, 2016 final rule as published and will provide technical amendments to further align the EPA’s TSCA Title VI program with the CARB ATCM Phase II program. This action will relieve or have no net regulatory burden for directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132. 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.

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

This action does not have tribal implications as specified in Executive Order 13175. This proposed rule would not impose substantial direct compliance costs on Indian tribal governments. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: 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 Executive Order 13045 has the potential to influence the regulation. As addressed in Unit II.A., this action would not significantly alter the December 12, 2016 final rule as published and proposes technical amendments to further align the EPA’s TSCA Title VI program with the CARB ATCM Phase II program.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NNTAA) and 1 CFR Part 51

This action involves technical standards. EPA is proposing the use of the following voluntary consensus standards issued by International Organization for Standardization/International Electrotechnical Commission:

1. ISO/IEC 17011:2017(E) Conformity assessments—requirements for accreditation bodies accrediting conformity assessments bodies
2. ISO/IEC 17025:2017(E) General requirements for the competence of testing and calibration laboratories

Copies of the standards referenced in the proposed regulatory text at § 770.3 and § 770.7 have been placed in the docket for this proposed rule. You may also obtain copies of these standards from the International Organization for Standardization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH–1211, Geneva 20, Switzerland, or by calling +41–22–749–01–11, or at http://www.iso.org. Additionally, each of these standards is 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. The following voluntary consensus standards are being updated: In the final rule, EPA intends to seek approval from the Director of the Federal Register for the incorporation by reference of the standards referenced in the final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

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

EPA has determined that this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The Agency presented the results of an environmental justice analysis in the December 12, 2016 TSCA Title VI final rule economic analysis (see EPA–HQ–OPPT–2016–0461–0028) and determined that the final rule did not have disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action would not significantly alter the final rule or the environmental justice analysis. The environmental justice analysis monetized the benefits from reducing the number of cases of nasopharyngeal cancer and sensory irritation and included an environmental justice analysis that expanded on the primary benefits analysis by analyzing the monetized impacts specifically for minority and low-income populations. This action will propose technical amendments to further align the EPA’s TSCA Title VI program with the CARB ATCM Phase II program.

List of Subjects in 40 CFR Part 770

Environmental protection, Formaldehyde, Incorporation by reference, Reporting and recordkeeping requirements, Third-party certification, Toxic substances, Wood.


Charlotte Bertrand,
Acting Principal Deputy Assistant Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, of the Code of
Federal Regulations be amended as follows:

PART 770—[AMENDED]

1. The authority citation for part 770 continues to read as follows:


2. In § 770.2, revise paragraphs (e) introductory text and (e)(1) and (4) to read as follows:

§ 770.2 Effective dates.

(e) Beginning June 1, 2018, all manufacturers (including importers), fabricators, suppliers, distributors, and retailers of composite wood products, and component parts or finished goods containing these materials, must comply with this part, subject to the following:

(1) Beginning June 1, 2018, laminated product producers must comply with the requirements of this part that are applicable to fabricators.

* * * * *

(4) Composite wood products manufactured (including imported) before June 1, 2018 may be sold, supplied, offered for sale, or used to fabricate component parts or finished goods at any time.

* * * * *

§ 770.3 [Amended]

3. In § 770.3:

a. In the terms “Assessment,” “Reassessment,” “TPC Laboratory,” “Surveillance On-Site Assessment” remove “17011:2004(E)” and add in its place “17011:2017(E);” and,

b. In the terms “EPA TSCA Title VI Laboratory Accreditation Body or EPA TSCA Title VI Laboratory AB” and “TPC Laboratory,” remove “17025:2005(E)” and add in its place “17025:2017(E);”

4. In § 770.7:


b. In paragraphs (a)(5)(i)(F), (b)(1)(iii), (b)(5)(i), (b)(5)(i)[A], (c)(1)(ii), (c)(2)(iv), remove “ISO/IEC 17025:2005(E)” and add in its place “ISO/IEC 17025:2017(E);” and,

c. Revise paragraph (c)(4)(v)(C).

The revision reads as follows:

§ 770.7 Third party certification.

* * * * *

(c) Notification of a panel producer exceeding its established QCL for three consecutive quality control tests within 72 hours of the time that the TPC becomes aware of the third exceedance.

The notice must include the product type, dates of the quality control tests that exceeded the QCL, quality control test results, ASTM E1333–14 (incorporated by reference, see § 770.99) or ASTM D6007–14 method (incorporated by reference, see § 770.99) correlative equivalent values in accordance with § 770.20(d), the established QCL value(s) and the quality control method used.

* * * * *

5. In § 770.10, revise paragraph (a) to read as follows:

§ 770.10 Formaldehyde emission standards.

(a) Except as otherwise provided in this part, the emission standards in this section apply to composite wood products sold, supplied, offered for sale, or manufactured (including imported) on or after June 1, 2018 in the United States. These emission standards apply regardless of whether the composite wood product is in the form of a panel, a component part, or incorporated into a finished good.

* * * * *

6. In § 770.12, revise paragraph (a) to read as follows:

§ 770.12 Stockpiling.

(a) The sale of stockpiled inventory of composite wood products, whether in the form of panels or incorporated into component parts or finished goods, is prohibited after June 1, 2018.

* * * * *

7. In § 770.15, revise paragraphs (a), (c)(1)(vii) and (c)(2)(v) to read as follows:

§ 770.15 Composite wood product certification.

(a) Beginning June 1, 2018, only certified composite wood products, whether in the form of panels or incorporated into component parts or finished goods, are permitted to be sold, supplied, offered for sale, or manufactured (including imported) in the United States, unless the product is specifically exempted by this part.

* * * * *

(c) * * *

(1) * * *

(vii) Correlation data and linear regression equation (or, under the threshold approach, the correlation data and the upper limit); and

* * * * *

(2) * * *

(v) Correlation data and linear regression equation (or, under the threshold approach, the correlation data and the upper limit); and

* * * * *

8. In § 770.17, revise paragraph (a)(4) to read as follows:

§ 770.17 No-added formaldehyde based resin.

(a) * * *

(4) Three months of routine quality control tests under § 770.20, including a showing of correlation in accordance with § 770.20(d)(2), totaling not less than twelve quality control tests.

* * * * *

9. In § 770.18, revise paragraph (a)(4) to read as follows:

§ 770.18 Ultra low-emitting formaldehyde based resins.

(a) * * *

(4) Six months of routine quality control tests under § 770.20, including a showing of correlation in accordance with § 770.20(d)(2), totaling not less than twenty-six quality control tests.

* * * * *

10. In § 770.20:

a. Add paragraph (c)(2)(iv);

b. Revise paragraphs (d) and (d)(1);

c. Add paragraphs (d)(1)(iv) and (d)(1)(iv)(A) through (C);

d. Revise paragraphs (d)(2) introductory text and (d)(2)(i); and

e. Add paragraphs (d)(2)(i)(A) and (B).

The additions and revisions read as follows:

§ 770.20 Testing requirements.

* * * * *

(c) * * *

(2) * * *

(iv) Test results may represent a single chamber value or, the average value of testing nine specimens representing evenly distributed portions of an entire panel. The nine specimens must be tested in groups of three specimens, resulting in three test values, which must be averaged to represent one data point for the panel those specimens represent.

* * * * *

(d) Equivalence or correlation.

Equivalence between ASTM E1333–14 (incorporated by reference, see § 770.99) and ASTM D6007–14 (incorporated by reference, see § 770.99) must be demonstrated by EPA TSCA Title VI TPCs at least once each year or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel, or reason to believe that the equivalence is no longer valid. Equivalence may be demonstrated between several similar model or size and construction ASTM E1333–14 (incorporated by reference, see § 770.99) and ASTM D6007–14 (incorporated by reference, see § 770.99) apparatuses located in the same EPA TSCA Title VI TPC laboratory. Once
equivalence has been established for three consecutive years, equivalence must be demonstrated every two years or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel. Correlation between ASTM E1333–14 (incorporated by reference, see § 770.99) or, upon a showing of equivalence in accordance with paragraph (d) of this section, ASTM D6007–14 (incorporated by reference, see § 770.99) and any other test method used for quality control testing must be demonstrated by EPA TSCA Title VI TPCs or panel producers, respectively, before the certification of composite wood products, and then whenever there is a significant change in equipment, procedure, the qualifications of testing personnel, or reason to believe that the correlation is no longer valid. Correlation may be established between several similar model or size and construction mill quality control test methods defined in § 770.20(b)(1) located at any one physical mill quality control testing laboratory to the EPA TSCA Title VI TPC's laboratory's ASTM E1333–14 (incorporated by reference, see § 770.99) and/or ASTM D6007–14 (incorporated by reference, see § 770.99) apparatus. If the TPC's laboratory's ASTM E1333–14 or equivalent ASTM D6007–14 test chamber is used for panel producer quality control testing, no correlation as determined in § 770.20(d)(2) would be required.

(1) Equivalence between ASTM E1333–14 and ASTM D6007–14 when used by the TPC for quarterly testing. Equivalence must be demonstrated for at least five comparison sample sets in each range tested by the TPC, which compare the results of the two methods. Equivalence must be demonstrated for any ranges listed in § 770.20(d)(1)(iv) that represent the formaldehyde emissions of composite wood products tested by the TPC.

(iv) Equivalence Ranges. EPA TSCA Title VI TPCs must demonstrate equivalence in at least two of the three formaldehyde emission ranges listed in (d)(1)(iv)(A) through (C) of this section unless the EPA TSCA Title VI TPC will only certify products in one range. If the EPA TSCA Title VI TPC will only certify products in one range, the EPA TSCA Title VI TPC may demonstrate equivalence in only that one range and would then be restricted to only certifying composite wood products in that range. Equivalence in one range must be demonstrated for at least five comparison sample sets in that range which compare the two methods.

(A) Lower Range: Less than, or equal to 0.05 ppm.
(B) Intermediate Range: Greater than 0.05 ppm to less than or equal to 0.15 ppm.
(C) Upper Range: Greater than 0.15 to 0.25 ppm.

(2) Correlation between ASTM E–1333–14 (incorporated by reference, see § 770.99), or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99), and any quality control test method. Correlation must be demonstrated by establishing an acceptable correlation coefficient (‘r’ value) or following the threshold approach at § 770.20(d)(2)(i)(B).

(i) Correlation. The correlation must be based on a minimum sample size of five data pairs and a simple linear regression (unless the threshold approach at § 770.20(d)(2)(i)(B) is used) where the dependent variable (Y-axis) is the quality control test value and the independent variable (X-axis) is the ASTM E1333–14 (incorporated by reference, see § 770.99) test value or, upon a showing of equivalence in accordance with paragraph (d) of this section, the equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test value. Either composite wood products or formaldehyde emissions reference materials can be used to establish the correlation.

(A) Cluster Approach. A panel producer may work with its EPA TSCA Title VI TPC to develop a correlation and linear regression between the TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b). In the event of clustered test results, a panel producer may fit a line through a point near the origin (the intersection of the X and Y axes) and the average value of the clustered data pairs. The point near the origin should represent the value for the EPA TSCA Title VI TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b) as the quality control limit for the product. The line between the point near the origin and the average value of the cluster provides the linear regression. This line may be used by the panel producer and TPC to develop a quality control limit for the product.

(B) Threshold Approach. As an alternative to the linear regression and cluster approaches, a panel producer may use the average value of the clustered data pairs from the EPA TSCA Title VI TPC's ASTM E1333–14 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–14 (incorporated by reference, see § 770.99) test method and the panel producer's quality control method under § 770.20(b) as the quality control limit for the product. In this approach, no linear regression line is established. The average value would be assigned as the upper limit for production of the subject composite wood product, providing a margin of safety relative to the maximum value of the data cluster. This value, established as the quality control limit, must be below the applicable emission standard.

* * * * *

11. In § 770.22, revise paragraph (c)(2)(i) and add paragraph (f)(1) to read as follows:

§ 770.22 Non-complying lots.

* * * * *

(c) * * *

(ii) At least one test panel must be randomly selected so that it is representative of the entire non-complying lot and is not the top or bottom panel of a bundle. Panel sampling shall be conducted according to the quarterly testing procedure at § 770.20(c)(2)(iv). The panel may be selected from properly stored samples set aside by the panel producer for retest in the event of a failure.

* * * * *

(f) * * *

(1) If a fabricator, importer, distributor, or retailer is notified that they have been supplied a non-complying lot after those composite wood products have been fabricated into component parts or finished goods, the notification requirement at paragraph (d)(1) of this section does not apply.

12. In § 770.30, revise paragraphs (b) introductory text and (c) to read as follows:

§ 770.30 Importers, fabricators, distributors, and retailers.

* * *

(b) Importers must demonstrate that they have taken reasonable precautions
by maintaining, for three years, bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or were produced before June 1, 2018 and by ensuring the following records are made available to EPA within 30 calendar days of request:

(c) Fabricators, distributors, and retailers must demonstrate that they have taken reasonable precautions by obtaining bills of lading, invoices, or comparable documents that include a written statement from the supplier that the composite wood products, component parts, or finished goods are TSCA Title VI compliant or that the composite wood products were produced before June 1, 2018.

§ 770.99 Incorporation by reference.

1. In §770.99, revise paragraphs (e)(1) and (3) to read as follows:


§ 770.45 Labeling.

(a) Panels or bundles of panels that are imported, sold, supplied, or offered for sale in the United States must be labeled with the panel producer’s name, the lot number, the number of the EPA TSCA Title VI TPC, and a statement that the products are TSCA Title VI certified or, for products exempt from certain testing and certification pursuant to §§770.17 or 770.18, a statement that the products are TSCA Title VI compliant or were produced before June 1, 2018.

(b) The label must include (e.g., color-coded edge marking) sufficient to identify the supplier of the panel and linking the information on the label to the products. This information must be made available to potential customers upon request. The label may be applied as a stamp, tag, or sticker.

(f) All panels (or bundles of panels) and finished goods (or boxes or bundles containing finished goods) must be properly labeled pursuant to paragraphs (a), (b), and (c) of this section before being imported into the United States, except as provided in paragraph (e) of this section.

§ 770.99 Incorporation by reference.

(a) Incorporate by reference the following documents:
