classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 5, 2016.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

Parts 52 and 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.1885 is amended by adding paragraph (pp)(2) to read as follows:

§ 52.1885 Control strategy: Ozone.

* * * * *

(pp) * * *

(2) Approval—On June 16, 2016, the Ohio Environmental Protection Agency submitted a request to redesignate the Columbus area to attainment of the 2008 ozone NAAQS. As part of the redesignation request, the State submitted a maintenance plan as required by section 175A of the Clean Air Act. Elements of the section 175 maintenance plan include a contingency plan and an obligation to submit a subsequent maintenance plan revision in eight years as required by the Clean Air Act. The 2020 motor vehicle emissions budgets for the Columbus area are 50.66 tons per summer day (TPSD) for VOC and 90.54 TPSD for NO_X. The 2030 motor vehicle emissions budgets for the Columbus area are 44.31 TPSD for VOC and 85.13 TPSD for NO_X.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. Section 81.336 is amended by revising the entry for Columbus, OH in the table entitled ''Ohio—2008 8-Hour Ozone NAAQS (Primary and secondary)'' to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—2008—8-HOUR OZONE NAAQS

[Primary and secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
*	*	*	*	*
Columbus, OH: [2] Delaware County, Fairfield County, Franklin County, Knox County, Licking County, Madison County.	December 21, 2016 ...	Attainment.		
*	*	*	*	*

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2016–30470 Filed 12–20–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 750

[HQ–OPPT–2016–0525; FRL–9955–15]

RIN 2070–AK28

Procedures for Rulemaking Under Section 6 of the Toxic Substances Control Act; Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Section 6 of the Toxic Substances Control Act (TSCA) provides EPA with several authorities for addressing risks from chemical substances and includes procedures that EPA must follow in doing so. EPA promulgated regulations shortly after TSCA was enacted to implement the procedural requirements for rulemaking under TSCA section 6 as they existed at that time. TSCA was recently amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This final rule removes the regulations specifying certain procedural requirements for rulemaking under TSCA section 6, including the requirement for a hearing, because TSCA, as amended, no longer mandates those procedures.

DATES: This final rule is effective December 21, 2016.

FOR FURTHER INFORMATION CONTACT: Cindy Wheeler, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 566–0484; email address: *wheeler.cindy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is the agency's authority for taking this action?

The authority for this action is TSCA section 6, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (15 U.S.C. 2605).

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(A), provides that ''rules of agency organization, procedure, or practice'' are exempt from notice and comment requirements. This action involves revisions to the rules that set out the general rulemaking procedure for EPA under the prior version of TSCA, and the action does not affect the substance of any determinations EPA will make under the amended TSCA section 6. Accordingly, these revisions fall under the exemption provided in APA section 553(b)(3)(A), and the EPA is not taking comment on this action.

B. Does this action apply to me?

This action affects only Agency procedure in future rulemakings under TSCA section 6 and has no particular applicability to the public. If you have any questions regarding the applicability of this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What action is the agency taking?

This action removes 40 CFR part 750, subpart A (the general procedural requirements for rulemaking under TSCA section 6, including the requirement for a hearing). Subpart A detailed hearing-related procedures as well as the content and timing of EPA's notices and the Agency's record. This action also removes the similar provisions from the procedural rules in subparts B and C for exemptions from the prohibitions in TSCA section 6(e) applicable to polychlorinated biphenyls.

TSCA, enacted in 1976, was intended to provide EPA with the tools necessary to develop information and manage risks associated with chemicals in commerce. TSCA section 6(a) requires EPA to take action to address unreasonable risks that EPA determines are presented by chemical substances or mixtures. Under TSCA section 6 as enacted in 1976, if EPA had a reasonable basis to conclude that the manufacture (including import), processing, distribution in commerce, use, or disposal of a chemical substance or mixture presented an unreasonable risk of injury to health or the environment, EPA would have to by rule apply requirements to the substance or mixture to the extent necessary to address the unreasonable risk using the least burdensome requirement. These requirements could include prohibitions or limitations on manufacturing processing, distribution in commerce, commercial use, or disposal; marking (labeling) requirements; and recordkeeping requirements. This section of TSCA also established certain procedures that EPA would have to follow in promulgating such rules. As enacted in 1976, TSCA section 6(c) required, among other things, that EPA provide the opportunity for an informal hearing and that EPA make certain findings and publish certain statements.

EPA published final procedural regulations to implement the TSCA section 6 procedural requirements shortly thereafter in the **Federal Register** of December 2, 1977, (42 FR 61259). These procedural regulations, codified as 40 CFR part 750, are quite detailed with respect to the contents of Notices of Proposed Rulemaking, hearing procedures, the handling of public comments, and docketing of comments and other supporting materials. These procedural requirements for rulemaking under TSCA section 6 have been amended several times, most notably in 1978 to add interim procedural rules for filing and processing petitions for exemptions from the TSCA section 6(e) ban on the manufacture of polychlorinated biphenyls (PCBs) (43 FR 50905, November 1, 1978), and in 1979 to add similar rules for petitions for exemptions from the TSCA section 6(e) bans on PCB processing and distribution in commerce (44 FR 31558, May 31, 1979).

On June 22, 2016, the President signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act into law. This legislation amends many sections of TSCA, including TSCA section 6. While the new law still directs EPA to take action against unreasonable risks presented by chemical substances or mixtures, EPA's duties under TSCA section 6 have been significantly modified to include specific deadlines and procedures for prioritizing chemicals for risk evaluations, conducting the risk evaluations and promulgating regulations to address unreasonable risks that are identified. Notably, once unreasonable risks have been identified through a risk evaluation, TSCA section 6(c)(1) now requires EPA to issue a proposed rule to address the risks no later than one year after the final risk evaluation is published, and the final rule must be issued no later than two years after the final risk evaluation is published, subject to the limited extension authorized by TSCA section 6(c)(1)(C).

After reviewing 40 CFR part 750 in light of the amendments to TSCA, EPA has determined that the procedural regulations in subpart A do not facilitate the efficient administrative process envisioned by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Subpart A was principally promulgated to provide further details related to the informal hearing process under TSCA as originally enacted. However, with the statutory amendments' removal of the informal hearing requirement and addition of ambitious deadlines for action under section 6, subpart A is particularly outdated and no longer designed for effective implementation of section 6. To the extent subpart A simply reflected administrative requirements of TSCA and the Administrative Procedure Act, the current version of TSCA and the Administrative Procedure Act will continue to apply on their own terms, and section 6 of TSCA as amended prescribes considerably more procedure than the previous version of TSCA. To the extent subpart A goes beyond the current statutory requirements of such law, EPA believes that the layering of additional procedural requirements by regulation is both unnecessary to ensure a transparent rulemaking process with robust public participation and not well-suited to the rapid throughput required by the law. EPA also believes the requirements are in some respects outdated with respect to current technology. The remainder of this notice elaborates on these points.

First, regarding the hearing-related provisions of 40 CFR part 750, TSCA section 6, as amended, no longer requires EPA to provide an opportunity for an informal hearing on a proposed rule. After TSCA was amended on June 22, 2016 and before this final rule, 40 CFR part 750 inaccurately referred to ''the informal hearing required by section 6(c)(2)(C) of TSCA'' when, in fact, TSCA section 6 no longer requires EPA to provide an opportunity for informal hearing and TSCA section 6(c)(2)(C) in particular now refers to another topic. Given that EPA is no longer required to provide an opportunity for an informal hearing on a proposed rule under TSCA section 6, and that the statutory citations in the hearing-related regulations are no longer correct, much of 40 CFR part 750 is no longer needed or appropriate.

Moreover, by establishing a two-year deadline for final rules after unreasonable risks are identified through risk evaluation, Congress expressed an intention for EPA to move relatively quickly to address unreasonable risks. Although Congress also established a limited process by which EPA could extend this deadline, EPA does not believe that Congress intended for extended deadlines to be a routine occurrence. The cumbersome nature of the informal hearing-related provisions established in 40 CFR part 750 would make it difficult for EPA to meet the newly-established rulemaking deadlines.

Yet EPA does not interpret the removal of the hearing requirement as an indication that reduced public input is desired. To the contrary, the amended TSCA section 6 specifically requires public comment periods at several stages during the chemical prioritization, risk evaluation, and risk management processes. EPA interprets the removal of the informal hearing requirement as being motivated by Congressional intent to simplify and thereby quicken the pace of TSCA section 6 rulemaking, considering the establishment of new rulemaking deadlines and the manner in which the tools for managing EPA's administrative rulemaking process have evolved over the 40 years since TSCA was enacted (*e.g.,* the advent of electronic commenting). Under the Administrative

Procedure Act (5 U.S.C. 553), EPA must give interested persons an opportunity to participate in a legislative rulemaking by submitting written comments. In addition, for existing chemicals under TSCA, EPA often holds public meetings in order to solicit oral comments as well as written comments.

Next, while EPA must still consider and publish a statement on certain factors when promulgating a rule under TSCA section 6(a), the factors have changed. For example, TSCA section 6(c) as originally enacted required EPA to consider and publish a statement with respect to the availability of substitutes for various uses of a chemical substance or mixture. TSCA section 6(c) as amended requires EPA to, in deciding whether to prohibit or restrict a chemical substance or mixture in a manner that substantially prevents a specific condition of use, and in setting an appropriate transition period for such chemical substance or mixture, consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. Therefore, EPA is removing the outdated specification of the content and timing of EPA notices in 40 CFR part 750, subpart A, and instead EPA's notices in future section 6 rulemakings will conform to TSCA as amended.

As EPA noted in 1987 (52 FR 23054), the initiation of a section 6 proceeding could be by proposed rule, advance notice of proposed rulemaking, or notice of other appropriate action. The agency is not changing its position on this matter by removing 40 CFR 750.2(a). As the agency stated previously, ''Federal courts have acknowledged that rulemaking commences before the publication of a notice of proposed rulemaking. See, for example, *Natural Resources Defense Council* v. *EPA,* 595 F. Supp. 1255 (S.D.N.Y. 1984), where the court found that EPA may use an ANPR to initiate a rulemaking proceeding under section 4 of TSCA.'' Therefore, the provision regarding when a proceeding begins does not need to be codified in the CFR.

Lastly, modern electronic tools and remote conferencing were not available when TSCA was enacted nor when procedural requirements under 40 CFR part 750 regarding Agency records were promulgated by EPA. EPA believes that it is now reasonable and prudent to use its information resources, including information technology, to establish an electronic record to contain rulemaking documents being considered and public comments submitted, a possibility not anticipated by the outdated record provisions. Consistent with TSCA section 2's expression of Congressional intent that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the environmental, economic, and social impacts that any action taken under TSCA may have, (15 U.S.C. 2601), electronic correspondence can reduce burden and costs for the regulated entities by eliminating the costs associated with printing and mailing documents, and traveling to hearings, while at the same time improving EPA's efficiency in reviewing public comments, making decisions, and disseminating information to the public.

Therefore, after considering the points discussed earlier in this notice, EPA is removing the general TSCA section 6 procedural requirements contained in subpart A of 40 CFR part 750. EPA is not making any changes to the procedures contained in subparts B and C of 40 CFR part 750 for petitions for exemptions from the prohibitions in TSCA section 6(e), other than to remove references to the informal hearing-related procedures as well as the content and timing of EPA's notices and the Agency's record corresponding to the removal of subpart A.

III. 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 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities that require approval under the PRA, 44 U.S.C. 3501 *et seq.* This rulemaking removes unnecessary internal EPA procedures and does not impose any requirements on the public.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute.

D. Unfunded Mandates Reform Act

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. This action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it merely removes procedural requirements that the Agency must follow when conducting rulemaking under TSCA section 6. Thus, Executive Order 13175 does not apply to this action.

G. 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 environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

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

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

This action does not establish an environmental health or safety standard, and is therefore not is not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This regulatory action is a procedural change and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This rule is exempt from the CRA (5 U.S.C. 801 *et seq.*) because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 750

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances.

Dated: December 8, 2016.

Gina McCarthy,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 750—PROCEDURES FOR RULEMAKING UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT [AMENDED]

■ 1. The authority citation for part 750 continues to read as follows:

Authority: 15 U.S.C. 2605.

Subpart A—[Removed and Reserved]

■ 2. Subpart A, consisting of §§ 750.1 through 750.9 and an appendix, is removed and reserved.

■ 3. Revise § 750.10 to read as follows:

§ 750.10 Applicability

Sections 750.10–750.15 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions filed pursuant to § 750.11(a).

■ 4. Revise § 750.13 to read as follows:

§ 750.13 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.11(a) shall begin with the publication of a notice of proposed rulemaking in the **Federal Register**. The notice shall state in summary form the required information described in § 750.11(c). Due to time constraints, the notice need not indicate what action EPA proposes to take on the exemption petitions.

§§ 750.14 and 750.15 [Removed]

■ 5. Remove §§ 750.14 and 750.15.

§ 750.16 [Redesignated as § 750.14]

■ 6. Redesignate § 750.16 as § 750.14.

§§ 750.17 through 750.20 [Removed]

■ 7. Remove §§ 750.17 through 750.20.

§§ 750.21 [Redesignated as § 750.15]

■ 8. Redesignate § 750.21 as § 750.15, and revise it to read as follows:

§ 750.15 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.11.

(c) In determining whether to grant an exemption to the PCB ban, the Agency shall apply the two standards enunciated in TSCA section 6(e)(3)(B).

■ 9. Revise § 750.30 to read as follows:

§ 750.30 Applicability

Sections 750.30 through 750.35 apply to all rulemakings under authority of section 6(e)(3)(B) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2605(e)(3)(B) with respect to petitions for PCB processing and distribution in commerce exemptions filed pursuant to § 750.31(a).

■ 10. Revise § 750.33 to read as follows:

§ 750.33 Notice of proposed rulemaking.

Rulemaking for PCB exemptions filed pursuant to § 750.31(a) shall begin with the publication of a notice of proposed rulemaking in the **Federal Register**. The notice shall state in summary form the required information described in § 750.31(c).

§§ 750.34 and 750.35 [Removed]

■ 11. Remove §§ 750.34 and 750.35.

§ 750.36 [Redesignated as § 750.34]

■ 12. Redesignate § 750.36 as § 750.34.

§§ 750.37 through 750.40 [Removed]

■ 13. Remove §§ 750.37 through 750.40.

§ 750.41 [Redesignated as § 750.35]

■ 14. Redesignate § 750.41 as § 750.35, and revise it to read as follows:

§ 750.35 Final rule.

(a) [Reserved]

(b) EPA will grant or deny petitions under TSCA section 6(e)(3)(B) submitted pursuant to § 750.31.

(c) In determining whether to grant an exemption to the PCB ban, EPA will apply the two standards enunciated in TSCA section 6(e)(3)(B).

[FR Doc. 2016–30055 Filed 12–20–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6072–N]

Medicare Program; Implementation of Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Publication of the Initial Required Prior Authorization List of DMEPOS Items That Require Prior Authorization as a Condition of Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Implementation of list and phases.

SUMMARY: This document announces the implementation of the prior authorization program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items in two phases and the issuance of the initial Required Prior Authorization List of DMEPOS items that require prior authorization as a condition of payment.

DATES: Phase one of implementation is effective on March 20, 2017. Phase two of implementation is effective on July 17, 2017.

FOR FURTHER INFORMATION CONTACT: Jennifer Phillips, (410) 786–1023. Linda O'Hara (410) 786–8347. Scott Lawrence (410) 786–4313.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Social Security Act (the Act) establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(15) of the Act authorizes the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items.

In the December 30, 2015 final rule (80 FR 81674), titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment,