FURTHER INFORMATION CONTACT section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, New Source Review, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 11, 2018.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, 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.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(458)(i)(A)(*2*) and (c)(509) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(458) * * *

(i) * * *

(A) * * *

(*2*) Previously approved on May 1, 2015 in paragraph (c)(458)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(509)(i)(A)(*1*), Rule 1325.

* * * * *

(509) New and amended regulations for the following APCDs were submitted on May 8, 2017 by the Governor's designee.

(i) *Incorporation by reference.* (A) South Coast Air Quality Management District.

(1) Rule 1325, ''Federal $PM_{2.5}$ New Source Review Program'' amended on November 4, 2016.

(*2*) [Reserved]

(B) [Reserved]

(ii) [Reserved]

* * * * *

■ 3. Section 52.248 is amended by adding paragraph (f) to read as follows:

§ 52.248 Identification of plan—conditional approval.

* * * * *

(f) The EPA is conditionally approving a California State Implementation Plan (SIP) revision submitted on May 8, 2017, updating Rule 1325—Federal $PM_{2.5}$ New Source Review Program, for the South Coast Air Quality Management District. The conditional approval is based on a commitment from the State to submit a SIP revision that will correct the identified deficiencies. If the State fails to meet its commitment by December 30, 2019, the conditional approval is treated as a disapproval.

* * * * *

[FR Doc. 2018–25900 Filed 11–29–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, and 262

[EPA–HQ–OLEM–2018–0646; FRL9986–91–OLEM]

Safe Management of Recalled Airbags

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule with request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is issuing this interim final rule in response to the urgent public health issue posed by recalled Takata airbag inflators still installed in vehicles. With this rule, EPA is facilitating a more expedited removal of defective Takata airbag inflators from vehicles by dealerships, salvage yards and other locations for safe and environmentally sound disposal by exempting the collection of airbag waste

from hazardous waste requirements so long as certain conditions are met. The Agency is also seeking comment on this interim final rule.

DATES: This interim final rule is effective on November 30, 2018. Comments must be received on or before January 29, 2019. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions must be received on or before January 29, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2018–0646, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, MC 5304P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460, Tracy Atagi, at (703) 308–8672, (*atagi.tracy@epa.gov*).

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. General Information

A. Does this action apply to me?

This action applies to entities that manage airbag waste (*i.e.,* discarded airbag modules and airbag inflators) that are subject to hazardous waste regulations. The dealerships performing the Takata recall work constitute the majority of the facilities that will be impacted by this rule. These dealerships fall under NAICS code 441: Motor Vehicle and Parts Dealers. EPA estimates that about 15,256 dealerships may be affected by this rule. Other potentially affected entities include those in NAICS code 336: Transportation Equipment Manufacturing, and in NAICS code 562: Waste Management and Remediation Services.

B. Why is EPA issuing an interim final rule?

Section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for issuing this interim final rule without prior proposal and opportunity for comment because such notice and opportunity for comment would be impracticable and contrary to the public interest. Specifically, prompt promulgation of this rule without delay is necessary to protect human health and the environment by facilitating the urgent removal of dangerously defective Takata airbag inflators from vehicles, and by preventing defective Takata airbag inflators from scrap vehicles from being reused, while maintaining protection of human health and the environment during airbag waste collection, storage and disposal.

In its November 3, 2015 Coordinated Remedy Order, the U.S. Department of Transportation (DOT) National Highway Traffic Safety Administration (NHTSA) found that it was imperative to accelerate the rate of the recalls because ''[e]ach airbag inflator with the capacity to rupture, as the recalled Takata inflators do, presents an unreasonable risk of serious injury or death . . . Since the propensity for rupture increases with the age of the inflator, and increases even more when the vehicle has been exposed to consistent long-term HAH [high absolute humidity] conditions, the risk for injurious or lethal rupture increases with each passing day.'' [1] This report emphasizes that as the inflators get older, each day that passes brings forth an increased danger. In addition, as noted in a November 15, 2017 report prepared by the Independent Monitor for the Takata Restructuring on *The State of the Takata Recalls,* ''[t]he words 'grenade' and 'ticking time bomb' accurately convey the lethal potential of these defective inflators.'' [2]

Delaying promulgation of this rule through notice and comment procedures would be impracticable and contrary to the public interest because such a delay would further increase the risk of death or serious injury by slowing down the removal of defective Takata airbag inflators from vehicles and impeding the collection of defective airbag inflators from salvage yards and other locations (and increasing the potential for defective airbag inflators in scrap vehicles to be reused). This existing risk has now increased significantly since the date of the 2015 NHTSA report because of recent events that further heighten the urgency to accelerate the recall.

First, more time has passed since the date of the 2015 NHTSA study, and as noted in that study and reiterated in the 2017 study by the Independent Monitor, each passing day brings forth more danger. The danger is greater today than in 2015 because of the increased age of the inflators.

Second, with the recent amendment to DOT's Preservation Order on April 12, 2018, and with Takata's restructuring due to bankruptcy finalized on February 21, 2018, vehicle manufacturers no longer have to send recalled inflators to Takata warehouses

[1] National Highway Traffic Safety Administration (NHTSA), *Coordinated Remedy Order,* November 3, 2015, Docket No. NHTSA–2015–0055, paragraph 32. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/nhtsa-coordinatedremedyorder-takata.pdf.*

[2] The Independent Monitor of Takata and the Coordinated Remedy Program, *The State of the Takata Airbag Recalls,* November 15, 2017, page 1, paragraph 1. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/the_state_of_the_takata_airbag_recalls-report_of_the_independent_monitor_112217_v3_tag.pdf.*

for long-term storage but may now send them directly for disposal. EPA is encouraging this through today's conditional exemption, since long-term storage of recalled inflators can make the defect more dangerous. These recalled inflators that are sent directly to disposal are not covered by the amended Preservation Order and thus are regulated as hazardous waste, whereas in the past they were not regulated as waste under the original Preservation Order. As a result, many automobile dealers and other entities who continue to replace recalled airbag inflators at the current rate of repair could become subject to additional hazardous waste generator requirements in 40 CFR part 262, which would impose additional regulatory obligations on the dealers' and salvage vendors' management of the inflators. Through our conversations with DOT, the automobile manufacturers, automotive salvage vendors, and other affected stakeholders, EPA has learned that imposing full generator requirements on automobile dealers and salvage vendors who lack the expertise and experience in managing hazardous waste would result in the slowdown, rather than the necessary acceleration, of the recall effort, resulting in even greater harm to human health and the environment.[3]

This rule is intended to assist the automobile dealers and other entities in their handling of the airbags, and ensure delivery of the airbags to facilities that can more expertly manage these airbags in order to accelerate the recall. Thus, it is essential that there be no delay in promulgating this rule.

Third, there have continued to be deaths as recently as 2018 as a result of Takata airbag explosions. On January 1, 2018, there was a death in Malaysia[4], and before that, on July 13, 2017, a death in Australia[5] as well as another on July 19, 2017 in Florida[6] as a result of defective Takata airbags.

Finally, with respect to the effective date, EPA finds that it has good cause to make the revisions immediately effective under section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. 553(d), and section 3010(b) of RCRA, 42 U.S.C. 6930(b). Section 553(d) provides in pertinent part that final rules shall not become effective until 30 days after publication in the **Federal Register**, ''except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction . . . or as otherwise provided by the agency for good cause''. RCRA section 3010(b) has similar provisions for an immediate effective date. It provides for an immediate effective date, rather than the usual six month period, for ''(1) a regulation with which the Administrator finds the regulated community does not need six months to come into compliance . . . . or (3) other good cause found and published with the regulation,'' among other exceptions.

The purpose of section 553(d) of the APA is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Similarly, as noted above, whether the regulated community needs a period of time to come into compliance is relevant to the application of RCRA section 3010(b). Because this rule grants a conditional exemption from certain RCRA hazardous waste requirements, it qualifies for the APA exemption for any rule that ''recognizes or grants an exemption or relieves a restriction'' as well as the RCRA exemption for any rule for which ''the regulated community does not need six months to come into compliance.''

Moreover, EPA has determined that for purposes of both the APA and RCRA effective date provisions, there is good cause for making this final rule effective immediately. In determining whether good cause exists to waive the 30-day effective date under the APA, an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling.'' *Gavrilovic,* 551 F.2d at 1105. EPA has also applied this balancing test to the RCRA effective date provision for purposes of this rule. This rule facilitates a more expedited removal of defective Takata airbag inflators from vehicles by dealerships, salvage yards and other locations for safe and environmentally sound disposal by exempting the collection of airbag waste from hazardous waste requirements so long as certain conditions are met. Because this action provides an exemption to certain requirements that automobile dealers and other parties would otherwise need to follow under RCRA, and because this exemption is optional, the regulated community does not need time to prepare for this rule. Specifically, as further discussed in this preamble, the conditions for the exemption mirror how recalled airbag modules and airbag inflators have been managed under the DOT Preservation Order during the past three years, and therefore no additional time is needed to start operating under the exemption. In contrast, the necessity of immediate implementation is great, as previously discussed.

As a result, EPA is making this interim final rule effective upon publication.

II. Statutory Authority

These regulations are promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3006, 3010, and 3017 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA). This statute is commonly referred to as ''RCRA.''

III. When will this interim final rule be effective?

The revisions to 40 CFR 260.10, CFR 261.4 and CFR 262.14 become effective on November 30, 2018.

IV. Background Information

A. Regulation of Airbag Modules and Airbag Inflators Under RCRA

An airbag module is a fully assembled unit including both the airbag inflator and the fabric cushion. An airbag inflator is the small metal canister within the airbag module that generally houses explosive propellant and an initiator. The airbag module is deployed when the airbag inflator receives an electronic pulse from a vehicle's crash sensor. In properly functioning airbag modules that use a gas generating system, chemical propellant contained in an airbag inflator unit burns in a fast and controlled manner, quickly emitting an inert gas through vents in the canister out into the airbag module, which inflates the cushion. Airbag modules across the automobile safety industry utilize explosive propellants for rapid response to an automobile accident.

Most airbag inflators use oxidizers as part of the gas generating composition of

[3] EPA 2018. *Compilation of Stakeholder Meeting Summaries Regarding RCRA Regulation of Airbag Waste.*

[4] *Confirmed Rupture of Takata Driver's Airbag Inflator in Malaysia on January 1, 2018* (Jan. 30, 2018), *https://www.honda.com.my/corporate/press_release_details/660/Confirmed-Rupture-of-Takata-Driver%E2%80%99s-Airbag-Inflator-in-Malaysia-on-January-1,-2018.*

[5] *Takata Recall: Sydney man was due to replace airbag two days before fatal accident* (last updated Sept. 6, 2018), *https://www.theguardian.com/world/2018/sep/07/takata-recall-sydney-man-was-due-to-replace-airbag-two-days-before-fatal-accident.*

[6] *20th death from faulty Takata airbags reported by Honda* (Dec. 20, 2017), *https://www.cbsnews.com/news/20th-death-from-faulty-takata-air-bags-reported-by-honda/.*

the propellant and, therefore, when discarded, would meet the definition of ignitable hazardous waste under the RCRA hazardous waste regulations at 40 CFR 261.21(a)(4), which states that a solid waste exhibits the characteristic of ignitability if, ''[i]t is an oxidizer.'' [7] In addition, due to the explosive propellant component, discarded airbag modules and airbag inflators meet the definition of reactive hazardous waste at 40 CFR 261.23(a)(6), which states that a solid waste exhibits the characteristic of reactivity if, ''[i]t is readily capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement.'' [8] The deployment of airbag inflators generally results in the depletion of the ignitable and/or reactive components to cause the release of inert gas, after which the inflators would no longer exhibit the ignitable or reactive characteristics under the RCRA regulations.

Airbag modules and airbag inflators that exhibit hazardous waste characteristics under 40 CFR part 261 subpart C may be exempt from hazardous waste regulations under certain scenarios, as summarized in an EPA memorandum signed on July 19, 2018.[9] As the memo explains, the applicable RCRA hazardous waste regulations for airbag modules and airbag inflators depend on the type of device, and how it is managed. However, it is important to note that, as the memo explains, recalled Takata airbag modules and airbag inflators removed from vehicles do *not* qualify for the exemptions and exclusions available to non-recalled airbag modules and airbag inflators because, as described in this preamble, the Takata recalled airbag inflators cannot be safely reused or deployed.

B. Background on the Takata Inflator Recalls

In May 2015, the U.S. Department of Transportation (DOT) announced a national recall of airbag inflators manufactured by Takata due to a defect in their phase-stabilized ammonium nitrate (PSAN) propellant, which has resulted in fifteen deaths and at least 250 injuries in the U.S. as of August 2018.[10] These airbag inflator recalls constitute the largest automotive recall in U.S. history, with 19 vehicle manufacturers affected and approximately 65–70 million airbag inflators scheduled to be recalled by December 2019. Of these affected airbag inflators, 50 million inflators in an estimated 37 million vehicles were recalled as of August 2018 and the remaining inflators will be recalled by December 2019.[11] Included in this number are tens of thousands of ''Alpha'' airbag inflators, which have a significantly higher risk of rupture due to a manufacturing defect resulting in low-density propellant in addition to the propellant defect described below. Nine of the 15 fatalities in the U.S. were caused by Alpha airbag inflators.[12]

On November 3, 2015, the National Highway Traffic Safety Administration (NHTSA) issued a Coordinated Remedy Order that set forth the requirements and obligations of certain motor vehicle manufacturers and the airbag manufacturer, Takata, in connection with the recall and remedy of certain types of Takata airbag inflators.[13] In its Coordinated Remedy Order, NHTSA found that it was imperative to accelerate the rate of the recalls because ''[e]ach airbag inflator with the capacity to rupture, as the recalled Takata inflators do, presents an unreasonable risk of serious injury or death. . . . Since the propensity for rupture increases with the age of the inflator, and increases even more when the vehicle has been exposed to consistent long-term HAH [high absolute humidity] conditions, the risk for injurious or lethal rupture increases with each passing day.'' [14]

The PSAN propellant used in the recalled Takata airbag inflators degrades over time when moist propellant is exposed to long-term daily temperature cycling. Moisture from the air adsorbs to PSAN particles, changing the structure of the propellant and causing the inflator to over-pressurize during deployment.[15] In some cases, this over-pressurization causes the metal canister to rupture, producing shrapnel-like metal shards during airbag inflation. To mitigate these effects, Takata began manufacturing PSAN airbag inflators containing desiccant to prevent the adsorption of moisture to the PSAN particles. While some inflators with desiccant have been recalled, others are still under evaluation and may or may not be recalled in the future.[16]

A 2015 Safety Data Sheet (SDS) for Takata pyrotechnic automotive safety devices, including airbag modules and airbag inflators, describes the hazards of the devices, including an ''[i]nitiation hazard of an uncontrolled activation of the safety device due to: Fire; heat; electrostatic discharge; inductions through electromagnetic radiation; or, excessive mechanical load'' and a ''[b]urn hazard when there is direct contact with pyrotechnic safety device during activations.'' [17] The firefighting measures described in the SDS include evacuating personnel and emergency responders for 1500 feet (⅓ mile). In the event of spilled material from damaged devices, the SDS recommends that an explosive expert conduct the cleanup using anti-static equipment.

Propagation and bonfire testing results submitted to EPA by Takata provides further information regarding the hazards posed by recalled Takata inflators.[18] In September 2016, a third-party company performed sympathetic propagation testing on two types of recalled Takata airbag inflators for Takata. The testing generally consisted of bundling several inflators together and deploying the center inflator in order to observe the effects of deployment on the surrounding inflators. The results of the testing showed that deployment of one inflator does not cause deployment of surrounding inflators. In some tests, the center inflator fragmented, but it still did not cause surrounding inflators to deploy or fragment, although some superficial damage to the surrounding inflators did occur. In April 2017, a third-party company performed the UN 6(c) external fire (bonfire) test on recalled Takata airbag inflators in individual fiberboard boxes. The inflators did not mass detonate when exposed to fire, but they did initiate, as

[7] Ignitable hazardous waste carries the waste code D001.

[8] Reactive hazardous waste carries the waste code D003.

[9] U.S. EPA, *Regulatory Status of Automotive Airbag Inflators and Fully Assembled Airbag Modules,* July 19, 2018.

[10] National Highway Traffic Safety Administration (NHTSA), *Takata Recall Spotlight. https://www.nhtsa.gov/equipment/takata-recall-spotlight.*

[11] Id.; National Highway Traffic Safety Administration (NHTSA), *The State of Takata Recalls, https://www.nhtsa.gov/recall-spotlight/state-takata-recalls.*

[12] National Highway Traffic Safety Administration (NHTSA), *Takata ''Alpha'' Airbags Pose Increased Risk, https://www.nhtsa.gov/recalls/takata-alpha-air-bags-pose-increased-risk.*

[13] National Highway Traffic Safety Administration (NHTSA), *Coordinated Remedy Order,* November 3, 2015, Docket No. NHTSA–2015–0055. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/nhtsa-coordinated remedyorder-takata.pdf.*

[14] Ibid, paragraph 32.

[15] National Highway Traffic Safety Administration (NHTSA), *Expert Report of Harold R. Blomquist, Ph.D.,* May 4, 2016. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/expert_report-hrblomquist.pdf.*

[16] National Highway Traffic Safety Administration (NHTSA), *New Takata recall involves Nissan, Ford, and Mazda vehicles, https://www.nhtsa.gov/recall-spotlight/new-takata-recall-involves-nissan-ford-and-mazda-vehicles.*

[17] Takata Safety Data Sheet (SDS)—Pyrotechnic Automotive Safety Devices, January 2015.

[18] Testing information was submitted as confidential business information (CBI). The summary of results in this preamble does not contain CBI.

would be expected when inflators are exposed to temperatures generated by this type of fire. In some cases, they were propelled from their initial locations of rupture, throwing fragments beyond the initial location of the inflator.

C. Damage Incidents Related to Airbag Inflator Recycling

While non-Takata airbag inflators do not present the same shrapnel-producing defect as recalled Takata airbag inflators, these airbag inflators can still present an explosive risk when processed or recycled, as demonstrated by recent incidents at two facilities. In February 2015, an explosion and fire occurred at one airbag manufacturing and recycling facility as two workers handled airbag inflators that had been processed in an incinerator prior to recycling the metal.[19] In that incident, one worker was hospitalized with head injuries and burns. In March 2018, a large explosion at a different airbag recycling facility in the dedicated airbag recycling area killed one worker and seriously injured another.[20] This explosion is suspected to have been caused by the ignition of aluminum dust, which was created in the process of shredding airbag inflators. These incidents demonstrate the characteristically hazardous nature of waste airbag inflators and their component materials and the potential risk they pose to human health during processing.

D. Impact of Takata Bankruptcy and the Amended Preservation Order on Management of Takata Inflators

2015 Preservation Order

A Preservation Order issued by DOT and signed by Takata in February 2015 required all recalled airbag inflators be preserved intact, except for those utilized for testing purposes. Takata was required to take all reasonable and appropriate steps designed to prevent the partial or full destruction, alteration, deletion, shredding, incineration or loss of recalled or returned inflators, ruptured inflators and any other inflators under the recalls. The recalled Takata inflators were organized into categories of inflators that must be preserved. Ruptured inflators from field events were required to be preserved in a locked, secured, climate-controlled area, except for testing, inspection or analysis purposes. Recalled or returned inflators were also to be kept in a locked, secured and climate-controlled area.

EPA June Memorandum

In the June 23, 2017 memorandum, EPA clarified that the recalled Takata airbag inflators are not subject to RCRA Subtitle C regulatory requirements while they are being held under the 2015 DOT Preservation Order because EPA does not consider materials being stored pending judicial proceedings or investigations to be ''discarded.'' This interpretation is consistent with previous interpretations EPA has taken on similar materials, such as seized fireworks held as evidence and materials from aircraft accidents subject to investigation, where such items would otherwise be considered hazardous waste.[21] [22] Additionally, EPA clarified that Takata recalled airbag inflators would be considered ''used'' (*i.e.,* spent materials), and therefore a solid waste, once the preservation requirements are lifted. When the recalled Takata airbag inflators are discarded as a solid waste, EPA believes that they meet both the ignitability and reactivity hazardous waste characteristics.[23]

Impact of Takata Bankruptcy on Recall Procedures

Takata's U.S. subsidiary, TK Holdings Inc., filed for Chapter 11 bankruptcy on June 25, 2017, and received U.S. court approval for its plan on February 21, 2018.[24] Takata's manufacturing assets were sold to Key Safety Systems, another automobile safety system manufacturer, and the money from the sale was used to settle debts and legal claims. A small portion of the company emerged from bankruptcy and has a section dedicated to facilitating the replacement of recalled airbag inflators.[25] Takata's plan sets aside funds designated for the removal, handling and eventual disposal of recalled airbag inflators received before the effective date of the bankruptcy, April 10, 2018, and states that Takata will continue to provide replacement airbag inflators until the recall process is finished, expected in 2020.[26] Takata will also continue to receive recalled airbag inflators for storage prior to testing or eventual disposal after April 10, 2018, although it is not required to do so. EPA's understanding is that Takata will charge the automobile manufacturers to cover the costs associated with storage and eventual disposal of these inflators received after April 10, 2018. These costs include the overhead expenses associated with Takata managing the collection, storage, and disposal of airbag inflators, including wages and benefits for their workers that are involved in handling and coordinating the movement of the inflators. Prior to the bankruptcy effective date, Takata accepted and managed these inflators from the affected vehicle manufacturers free of charge.

2018 Amended Preservation Order

The April 12, 2018 Amendment to the February 25, 2015 Preservation Order and Testing Control Plan, issued by the U.S. DOT's NHTSA, requires Takata to preserve certain airbag inflators that are the subject of an ongoing defect investigation by NHTSA and the subject of private litigation.[27] The Amendment also requires Takata to implement a control plan for the inspection, testing, or analysis of those inflators.

The original 2015 Preservation Order required Takata to preserve indefinitely all affected airbag inflators, while the 2018 Amendment enables Takata to reduce the number of preserved airbag inflators by requesting the release of certain inflators from the Preservation Order allowing them to be disposed in compliance with all applicable regulations, including RCRA. The Amended Order also requires Takata to account for returned foreign and other ammonium-nitrate containing inflators. The Amendment applies to Takata airbag inflators removed from vehicles as a result of recalls affecting the 19 vehicle manufacturers.

The terms of the Amendment require Takata to track all airbag inflators in its possession by unique serial number and set aside at least 5% of inflators,

[19] U.S. EPA, *Autoliv Promontory Facility (20 June 2017),* July 24, 2018.

[20] Tennessee Occupational Safety and Health Administration, *Redacted Report: Lighting Resources LLC Explosion on March 14, 2018,* August 16, 2018.

[21] U.S. EPA, *Explosives Presenting an Immediate Safety Threat and Explosives Stored During Analysis,* August 11, 1988. RCRA Online 11363.

[22] U.S. EPA, *Management of Aircraft Remains from Catastrophic Loss Events,* January 6, 2014. RCRA Online 14881.

[23] Ignitable waste code D001 (40 CFR 261.21(a)(4)). Reactive waste code D003 (40 CFR 261.23(a)(6)).

[24] Prime Clerk, *Takata TK Holdings Inc Bankruptcy Case Information, https://restructuring.primeclerk.com/takata/Home-Index.*

[25] To avoid confusion, the entities responsible for managing the Takata airbag inflator recalls, including Takata's post-bankruptcy successor company TK Global, will collectively be referred to as ''Takata'' in this preamble.

[26] U.S. Bankruptcy Court—District of Delaware, *Fifth Amended Joint Chapter 11 Plan of Reorganization of TK Holdings Inc. and its Affiliated Debtors,* filed February 20, 2018.

[27] National Highway Traffic Safety Administration (NHTSA), *Amendment to the February 25, 2015 Preservation Order and Testing Order Control Plan,* April 12, 2018, EA15–001 (formerly PE14–016). *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/preservation_order_amendment_public_-_april_12_2018-tag.pdf.*

proportionate to the overall number of inflators received from each State and of each type of inflator, for future analysis. The Amendment allows Takata to submit Disposal Designations to NHTSA, identifying a specific quantity of inflators to be released from preservation and disposed. The designated inflators are considered released from the Preservation Order fifteen business days after NHTSA's confirmation of receipt of the Disposal Designation.

Although the affected vehicle manufacturers may choose to contract with Takata's post-bankruptcy reorganized entity to transport and store recalled airbag inflators, they are not required to do so by the Preservation Order or Amendment. If a vehicle manufacturer chooses to contract with the Takata entity, the Takata entity must preserve those airbag inflators under the terms of the Preservation Order, and therefore those airbag inflators are not solid wastes per EPA's June 23, 2017 memorandum as described above. However, a vehicle manufacturer may choose not to contract with the Takata entity for a variety of reasons, including increased cost, increased liability, and slower disposal, in which case those airbag inflators would not be covered by the Preservation Order or Amendment, and would be considered discarded when removed from the vehicle.

V. Rationale for Conditional Exemption for Collection of Airbag Waste

In its 2015 Coordinated Remedy Order pertaining to the Takata airbag recalls, DOT found that it was imperative to accelerate the rate of the recalls because ''[e]ach airbag inflator with the capacity to rupture, as the recalled Takata inflators do, presents an unreasonable risk of serious injury or death. . .Since the propensity for rupture increases with the age of the inflator, and increases even more when the vehicle has been exposed to consistent long-term HAH [high absolute humidity] conditions, the risk for injurious or lethal rupture increases with each passing day.'' [28]

Since the original order was issued by DOT, the affected vehicle manufacturers have been working steadily to remove the recalled Takata airbag inflators from vehicles. As discussed earlier, because of DOT's Preservation Order, the recalled airbag inflators have not been regulated as hazardous waste and have instead been safely collected, transported as hazardous materials and stored under the Preservation Order.

With the amendment to DOT's Preservation Order and with Takata's restructuring due to bankruptcy, vehicle manufacturers may now dispose of recalled inflators that are not covered by the amended Preservation Order directly, rather than sending them to the Takata warehouses for long-term storage. This approach is preferable from a public health and environmental protection perspective both because it reduces the volume of inflators in long-term storage and because it is more efficient in freeing up resources spent on handling and storage that can be spent directly on the recalls themselves.

However, because this subset of recalled inflators is not subject to the DOT Preservation Order, they would be regulated as hazardous waste. As a result, many automobile dealers and other entities who continue to replace recalled airbag inflators at the current rate of repair would become subject to additional hazardous waste generator requirements in 40 CFR part 262, which would impose additional regulatory obligations on the dealers' and salvage vendors' management of the inflators.

Most automobile dealers and salvage vendors are currently in the category of ''Very Small Quantity Generators'' of hazardous waste. By managing hazardous airbag waste, the dealers and salvage vendors would likely generate sufficient amounts of hazardous waste (on a monthly basis) to become subject to increased regulations associated with higher generator categories for which dealers and salvage vendors typically have not had experience, familiarity, or expertise. Imposing these increased generator obligations on dealers and salvage vendors would result in a much less efficient, effective and environmentally protective approach to the urgent, time-critical recall effort. Through our conversations with DOT, the automobile manufacturers, automotive salvage vendors, and other affected stakeholders, EPA has learned that imposing full generator requirements on automobile dealers and salvage vendors who lack the expertise and experience in managing hazardous waste might result in the slowdown, rather than the necessary acceleration, of the recall effort, resulting in greater harm to human health and the environment.[29] The automobile manufacturers are worried that, because of their lack of familiarity and expertise with full RCRA hazardous waste generator regulations and the additional costs related to the management of hazardous waste in these higher generator categories, if the dealers were to become fully regulated small or large quantity generators due to handling recalled airbag waste, they may slow down or stop removing recalled airbag inflators altogether. In addition, some stakeholders have expressed their concern of a lack of hazardous waste transportation capacity, especially in more sparsely populated rural areas of the country. As hazardous waste generators, dealers would be required to use certified hazardous waste transporters, which are less numerous and more expensive than standard hazardous material transporters used to transport recalled inflators under the DOT preservation order. Thus, placing full hazardous waste generator requirements on dealers or salvage yards would not be the most efficient or environmentally protective approach for the above reasons. In contrast, as explained in the following section, an airbag waste collection facility under the control of a vehicle manufacturer or their authorized representative or under the control of an authorized party administering a remedy program in response to the recalls or a designated facility as defined in 40 CFR 260.10, has greater expertise and familiarity in properly managing hazardous waste.

A related but separate issue involves airbag modules and airbag inflators scavenged from scrapped automobiles. One vendor company has been involved in the collection of Takata airbag modules from the approximately 6,000 salvage yards in the United States. The company was approached by one automobile manufacturer after they discovered a number of injuries were caused by recalled Takata airbag inflators recovered from salvage yards and installed in other vehicles. The salvage vendor worked with the automobile manufacturer, DOT, and the independent monitor to put together a program to retrieve airbag modules containing recalled airbag inflators before the inflators can be removed and placed in another vehicle because at that point, they are virtually untraceable. The vendor collects the airbag and brings them to a central location where they undergo a validation step to determine whether they are definitively recalled airbag inflators. This validation includes using visual aids and scanning all VIN and serial numbers. The vendor also supplies specifically designed packaging and handles the

[28] National Highway Traffic Safety Administration (NHTSA), *Coordinated Remedy Order,* November 3, 2015, Docket No. NHTSA–2015–0055. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/nhtsa-coordinated remedyorder-takata.pdf.*

[29] EPA 2018. *Compilation of Stakeholder Meeting Summaries Regarding RCRA Regulation of Airbag Waste.*

transportation for the airbag modules. Once a pallet of validated airbag modules is collected (approximately 100–110 pieces), the pallet is sent for disposal and a certificate of destruction is provided. The airbag modules are transported in compliance with DOT hazardous materials regulations. According to this vendor, if the airbag modules must be handled as RCRA hazardous waste when removed from a vehicle in the salvage yard, the salvage yards would likely stop removing them.

Due to the potential for the replacement of defective Takata airbag inflators to slow down with the application of full RCRA generator requirements, EPA has determined that modified RCRA requirements are appropriate for automobile dealers, salvage yards, and other entities that are removing the recalled airbag inflators and facilitating the recalls.

As discussed earlier, any potential delay to the recalls presents an immediate public health threat, increasing the chances of death or serious injury due to a defective airbag deploying in a vehicle. Moreover, the system for managing the recalled airbag modules and inflators under the DOT Preservation Order over the last three years has provided for protection of human health and the environment during collection and transport of the airbag modules and inflators. Under the recalls, each individual recalled inflator is tracked by vehicle identification number, and subject to DOT packaging and transportation regulations. Vehicle manufacturers work with their dealers to make sure that the recalled inflators are quickly moved offsite and not over-accumulated, and have a strong incentive from a liability perspective to continue to do so in the future.

The conditions for the exemption promulgated by this rule mirror how recalled airbag modules and airbag inflators have been managed under the DOT Preservation Order during the past three years, except that instead of going to long-term storage under the Preservation Order, the collected airbag waste will be sent for safe disposal at a RCRA facility designated to receive hazardous waste per 40 CFR 260.10. Thus, exempting the collection of airbag waste from RCRA requirements, provided certain conditions are met, will result in an increase in protection of public health by facilitating the recalls, allowing the current airbag waste collection system to continue to safely collect the recalled inflators, and sending them directly to appropriate disposal facilities rather than to long-term storage facilities under the Preservation Order.

As previously explained in other rulemakings, EPA has authority under RCRA to issue conditional exclusions from the hazardous waste regulations. EPA has previously interpreted RCRA section 3001(a) to authorize the issuance of ''conditional exemptions'' from the requirements of RCRA Subtitle C, where it determines that ''a waste might pose a hazard only under limited management scenarios, and other regulatory programs already address such scenarios.'' 62 FR at 6636 (February 12, 1997); 66 FR at 27222–27223 (May 16, 2001). The final rule takes a similar approach to those earlier rules.

Section 3001(a) requires that EPA decide whether a waste ''should be subject to'' the requirements of RCRA Subtitle C. Hence, RCRA section 3001 authorizes EPA to determine when subtitle C regulation is appropriate. EPA has consistently interpreted section 3001 of RCRA to give it broad flexibility in developing criteria for hazardous wastes to enter or exit the Subtitle C regulatory system.

RCRA section 1004(5) further supports EPA's interpretation. This interpretation has also been upheld upon judicial review. See, *e.g., Military Toxics Project* v. *EPA,* 146 F. 3d 948 (DC Cir. 1998) (upholding conditional exemption for storage of military munitions, based on EPA determination that such wastes are subject to binding standards that meet or exceed RCRA standards, in addition to an institutional oversight process.) EPA has interpreted the statutory definition of hazardous waste in RCRA section 1004(5)(B) as incorporating the idea that a waste that is otherwise hazardous does not require regulation under RCRA so long as it is properly managed.

EPA has most recently provided a full discussion of EPA's authority for conditional exclusion from RCRA Subtitle C requirements in the preamble in its final rule entitled Hazardous Waste Management System: Conditional Exclusion for Carbon Dioxide (CO2) Streams in Geologic Sequestration Activities, 79 FR 350, 353–354 (January 3, 2014). Consistent with that rule, and other rules involving conditional exemptions, EPA has determined in this rule, as discussed above, that exempting the collection of airbag waste from RCRA requirements, provided certain conditions are met, will result in an increase in protection of public health by facilitating the recalls and allowing the current airbag waste collection system to continue to safely collect the recalled inflators. It is important to note, however, that this conditional exemption only applies to the storage and transport of airbag waste during collection. The final disposition of the hazardous airbag waste continues to be regulated under applicable RCRA Subtitle C hazardous waste regulations.

EPA has received requests from stakeholders to unconditionally exempt airbag modules and inflators from RCRA hazardous waste regulations.[30] However, EPA has determined, based on the nature of the waste and the damage cases that have occurred at airbag recycling facilities, an exemption for the final disposition of airbag waste would not be protective of human health and the environment. While the collection of intact airbag modules and inflators by vehicle manufacturers or their authorized representatives according to DOT requirements can be done safely without imposing RCRA requirements beyond the conditions of the exemption discussed in this preamble, processing the airbag inflator, which requires treatment of the ignitable and reactive propellant inside the inflator, is another matter. As discussed earlier, there have been at least two explosions at airbag recycling facilities, including one that resulted in a fatality, and in the case of the recalled Takata airbag inflators, the degraded nature of the propellant makes the potential for explosive reactions even worse. The protections provided by a RCRA Subtitle C hazardous waste permitted facility, including personnel training, inspections, contingency planning and emergency response, and an informed community through public participation address the risk of explosion from the end-of-life management of the collected airbag waste.

EPA solicits comment on the conditional exemption for airbag waste, including the applicability of the exemption and the specific requirements of this conditional exemption as explained in this preamble. EPA will consider these comments in determining whether any additional revisions to the regulation of airbag waste are necessary in the future.

VI. Summary of Requirements of the Conditional Exemption for the Collection of Airbag Waste

A. Applicability of Conditional Exemption

The new airbag waste conditional exemption found at 40 CFR 261.4(j) applies to all airbag waste (*i.e.,* airbag modules and airbag inflators) collected from auto dealers or other airbag waste handlers for the purpose of safe

[30] EPA 2018. *Compilation of Stakeholder Meeting Summaries Regarding RCRA Regulation of Airbag Waste.*

disposal. Entities that generate airbag waste under the conditional exemption are referred to as ''airbag waste handlers'' and can include automobile dealers, independent repair facilities, collision centers, and salvage and scrap yards.

The vast majority of items affected by the conditional exemption will be Takata airbag waste. As of August 2018, an estimated 50 million defective airbag inflators were under recall in approximately 37 million U.S. vehicles, with the potential for more recalls to be issued in the future.

However, EPA has determined that the conditional exemption should also apply to the collection of non-Takata airbag waste for the purpose of disposal, provided that the conditions of the exemption are met. Managing all airbag waste under the same protective requirements will avoid confusion, increase efficiency and will help prevent non-Takata airbag waste from being diverted into the municipal waste stream. Because non-Takata airbag waste is expected to be a much smaller volume waste than the recalled Takata airbag waste, in many cases automobile dealers that generate hazardous waste would be below the Very Small Quantity Generator threshold of 100 kilograms/month, which under the federal RCRA requirements in 40 CFR 262.14 would allow the non-Takata airbag waste to be disposed of in the municipal wastestream. Including these materials under the airbag waste conditional exemption is more protective of human health and the environment because it would encourage their disposal at hazardous waste management facilities. To make it clear that VSQGs have the option of managing their airbag waste under the airbag waste conditional exemption and sending their airbag waste to an airbag waste collection facility or a designated facility subject to the requirements of 40 CFR part 261.4(j), EPA is including a conforming change to the VSQG regulations at 40 CFR 262.14(a)(xi). (Note that the airbag waste conditional exemption does not prevent the airbag modules or airbag inflators from being managed under other applicable exemptions as explained in the July 2018 memo referenced in section IV.A. in this preamble) In addition, EPA also requests comment on expanding the applicability of the airbag waste exemption to include other similar propellent-actuated devices and their components. It would be helpful if commenters include detailed information on these additional wastestreams, including descriptions of the wastestreams, volumes generated, risks posed and current management practices.

B. Limits on Accumulation Times and Quantities at Airbag Waste Handlers

Based on information provided by automobile manufacturers, automobile dealers limit the quantity of recalled airbag modules and inflators stored onsite. According to one automobile manufacturer, guidance provided by Takata requires that dealers ship out the recalled airbag inflators that have been removed from vehicles every two weeks, or when the quantity reaches 200 inflators (*i.e.,* a small truckload).[31]

Limiting the quantity and accumulation times at airbag waste handlers for airbag waste prevents over-accumulation and limits the potential hazards posed by the inflators in case of a fire. Under the airbag waste exemption finalized in this action, airbag waste handlers are allowed to accumulate up to 250 airbag modules or airbag inflators for up to 180 days, whichever comes first. Limiting the quantity of airbag modules and airbag inflators accumulated onsite to 250 (*i.e.,* a little over one small truckload) allows the dealer and other airbag waste handlers to prepare one truckload for shipping while continuing to accumulate airbag waste for future shipments. The 180-day timeframe is based on the small quantity generator limits in 40 CFR 262.16, and addresses the future situation when the Takata recalls near completion, resulting in a slower turn-around in recalled inflators accumulated at the dealer. At that point it may take much longer to reach the 250-item limit, and the 180-day time limit ensures storage does not extend indefinitely, and that the airbag waste is safely disposed and not abandoned.

C. Packaging, Labeling and Transportation Requirements for Airbag Waste Handlers

During accumulation under the airbag waste exemption, airbag waste must be packaged in a container designed to address the risk posed by the airbag waste. Such a container would help reduce the potential for the airbag waste to react in case of a fire, and also reduce the projectile hazard if the defective Takata airbag inflators were to deploy. In most cases, this container would be the same container that the replacement airbag part was shipped in to the airbag handler, or, in the case of salvage yards, the container provided by the salvage recovery vendor. However, any container that meets DOT requirements for transporting the airbag items would meet the terms of the conditional exemption. Each container must be labeled ''Airbag Waste—Do Not Reuse.''

Airbag waste must be shipped directly to either (1) a designated facility as defined in 40 CFR 260.10, or (2) an airbag waste collection facility in the United States under the control of a vehicle manufacturer or their authorized representative, or under the control of an authorized party administering a remedy program in response to a recall under the National Highway Traffic Safety Administration. Airbag waste collection facilities may include part supply centers/parts distribution centers or any other facility authorized by vehicle manufacturers to collect their airbag waste and hold it for more than 10 days. (Airbag waste held at a transfer facility for less than 10 days is considered to be in transport and only subject to the DOT transportation regulations). Because the airbag waste is not subject to hazardous waste generator requirements under 40 CFR part 262 while at the airbag waste handler, the designated facility or the airbag waste collection facility that accepts the airbag waste from the airbag waste handler is considered the hazardous waste generator for the purposes of 40 CFR part 262 as the person whose act first causes a hazardous waste to become subject to the generator regulations.

D. Tracking and Recordkeeping Requirements for Airbag Waste Handlers

As a condition for exemption from RCRA hazardous waste requirements, airbag waste handlers must maintain at the facility and make available upon inspection certain records that document off-site shipments of airbag waste for a period of three years to help verify the airbag waste went to an appropriate destination. Specifically, for each shipment of airbag waste, the handler must maintain documentation of the date of each shipment, the name of each transporter, the type and quantity of airbag waste (*i.e.,* airbag modules or airbag inflators) shipped, and the name and address of the destination facility or airbag waste collection facility. This recordkeeping requirement may be fulfilled by ordinary business records, such as bills of lading, including electronic records. In addition, airbag waste handlers are required to maintain confirmations of receipt from the designated facility or airbag waste collection facility in order to verify that the airbag waste reached its intended destination and was not diverted. These receipts must be

[31] EPA 2018. *Compilation of Stakeholder Meeting Summaries Regarding RCRA Regulation of Airbag Waste,* Appendix 1.

maintained at the airbag waste handler for a period of three years. Specifically, the airbag waste handlers must maintain documentation of receipt that includes the name and address of the designated facility or airbag waste collection facility, the type and quantity of airbag waste (*i.e.,* airbag modules or airbag inflators) received, and the date which it was received. The Agency is not requiring a specific template or format for confirmations of receipt and anticipates that routine business records (*e.g.,* financial records, bills of lading, copies of DOT shipping papers, electronic confirmations of receipt, etc.) could contain the appropriate information sufficient for meeting this requirement. Note that these recordkeeping requirements will be implemented under an emergency Information Collection Request (ICR). Based on the public comments received on this rule, EPA will publish a separate revised ICR. See Section VIII.C in this preamble.

E. Prohibition on Reuse of Defective Airbag Modules and Airbag Inflators

While used airbag modules and used airbag inflators are not solid waste when reused for their intended purpose, in the case of airbag modules and airbag inflators that are subject to a recall under the National Highway Traffic Safety Administration, such reuse is not allowed under RCRA. Reuse of recalled Takata inflators is particularly dangerous due to the shrapnel producing defect that can cause death or serious injury when the airbag is deployed, even when the vehicle accident would otherwise be considered minor. As noted in a report by the Takata Independent Monitor, salvaged Takata inflators may pose an even greater risk than other defective Takata inflators due to possible exposure to high heat and humidity for an extended time in the scrap vehicles. In one case, a vehicle that was repaired with a salvaged Takata airbag inflator was involved in a minor accident. The resulting shrapnel from deployment of the defective resulted in serious injury to the driver. The family owning the car had no reasonable way of knowing that it contained a defective inflator.[32] Any person who reuses a defective inflator or causes it to be reused may therefore be placing another person in imminent danger of death or serious injury. Such a reuse would not meet the definition of legitimate recycling in 40 CFR 260.43 and would be considered sham recycling under 40 CFR 261.2(g). Specifically, because the defective airbag modules and airbag inflators cannot serve as an effective substitute for a commercial product, and do not otherwise provide a useful contribution per 40 CFR 260.43(a)(1), their reuse is considered to be sham recycling and prohibited under the hazardous waste regulations.

[32] National Highway Traffic Safety Administration (NHTSA), *The State of Takata Airbag Recalls—Report of the Independent Monitor,* November 15, 2017. *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/the_state_of_the_takata_airbag_recalls-report_of_the_independent_monitor_112217_v3_tag.pdf.*

VII. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize a qualified state to administer and enforce a hazardous waste program within the state in lieu of the federal program, and to issue and enforce permits in the state. A state may receive authorization by following the approval process described in 40 CFR 271.21 (see 40 CFR part 271 for the overall standards and requirements for authorization). EPA continues to have independent authority to bring enforcement actions under RCRA sections 3007, 3008, 3013, and 7003. An authorized state also continues to have independent authority to bring enforcement actions under state law.

After a state receives initial authorization, new federal requirements and prohibitions promulgated under RCRA authority existing prior to the 1984 Hazardous and Solid Waste Amendments (HSWA) do not apply in that state until the state adopts and receives authorization for equivalent state requirements. In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), new federal requirements and prohibitions promulgated under HSWA provisions take effect in authorized states at the same time that they take effect in unauthorized states. As such, EPA carries out the HSWA requirements and prohibitions in authorized states, including the issuance of new permits implementing those requirements, until EPA authorizes the state to do so.

Authorized states are required to modify their programs only when EPA enacts federal requirements that are more stringent or broader in scope than existing federal requirements. Under RCRA section 3009, states may impose standards that are more stringent or broader in scope than those in the federal program (see also 40 CFR 271.1(i)). Therefore, authorized states are not required to adopt new federal regulations that are considered less stringent than previous federal regulations or that narrow the scope of the RCRA program. Previously authorized hazardous waste regulations would continue to apply in those states that do not adopt ''deregulatory'' rules.

B. Effect on State Authorization of Interim Final Rule

The regulations finalized in this interim final rule are not promulgated under the authority of HSWA. Thus, the standards will be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their program. Pursuant to section 3009 of RCRA, states may impose more stringent regulations than the federal program. This rule eliminates specific hazardous waste requirements that would otherwise apply to airbag waste (airbag modules and airbag inflators) managed under the conditional exemption, and therefore, these changes are less stringent than the federal program and authorized states are not required to adopt them. However, if a state were, through implementation of state waiver authorities or other state laws, to allow compliance with the provisions of the conditional exemption in advance of adoption or authorization, EPA would not generally consider such implementation a concern for purposes of enforcement or state authorization. Of course, the state could not implement the requirements in a way that was less stringent than the federal requirements in this rule.

VIII. Statutory and Executive Order (E.O.) Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. This rule has been determined significant because it raises novel legal or policy issues arising out of a legal mandate, the President's priorities or the principles set forth in the Executive Order. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, ''Economic Assessment of the Safe Management of Recalled Airbags Rule'',

is available in the docket. This analysis estimates the impacts of the rule relative to two separate baseline scenarios. The first baseline scenario assumes that all aspects of the Preservation Order established between Takata and the Department of Transportation in February 2015 and amended in April 2018 will remain in effect until the completion of the recall process. The alternative baseline scenario assumes the removal of the Preservation Order provisions that allow dealerships to disregard the volume of recalled airbag inflators when determining their hazardous waste generator status (*e.g.,* LQG) under RCRA. For each baseline and for the rule, EPA created a monthly schedule in order to estimate the number of airbag inflators shipped, accumulated, and disposed of by affected entities. EPA then assigned unit costs for storage, transport, management, and disposal of airbag inflators for each scenario to estimate the cost savings associated with this regulation. The cost impacts of the rule were then calculated as the difference between post-rule costs and costs under each baseline scenario. In summary, this regulatory action is expected to result in a total cost savings between $7.6 million and $56.9. million for the duration of the Takata recalls, resulting in an estimated annual cost savings of $1.7 million to $13.0 million per year (discounted at 7%).

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been granted emergency approval by the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) that has been approved by OMB was assigned EPA ICR number 2589.02 and OMB Control Number 2050–0221. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The collection of information is necessary in order to ensure that the hazardous waste airbag modules and airbag inflators exempted under this rule are safely disposed of and that defective airbag modules and airbag inflators are not reinserted into vehicles where they would pose an unreasonable risk of death or serious injury. Information collection activities include requiring affected entities maintain copies of shipping records and confirmations of receipt for three years.

In addition to the emergency ICR which will implement the requirements for up to six months, EPA is also developing an ICR based on comments received on this rulemaking. Towards this goal, pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate.

Respondents/affected entities: The respondents will primarily be composed of automobile dealerships. These dealerships fall under NAICS code 441: Motor Vehicle and Parts Dealers.

Respondent's obligation to respond: The recordkeeping requirements for the interim final rule consist of maintaining at the airbag handler for no less than three years records of (1) all off-site shipments and (2) confirmations of receipt of airbag waste. The recordkeeping requirements may be fulfilled by ordinary business records, such as bills of lading, and are intended to allow the Agency to verify that the airbag waste reaches its intended destination and is not diverted back into vehicles. The statutory authority to require the recordkeeping activities derives from sections 2002, 3001, 3002, 3003, 3004, 3006, 3010, and 3017 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA).

Estimated number of respondents: EPA estimates that there will be 15,256 respondents per year.

Frequency of response: EPA estimates that average facility will make 3 relevant shipments per year over a 5-year period. The facilities must retain documentation for each shipment.

Total estimated burden: 4,200 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $130,791 (per year), includes $0 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. The APA exempts from notice and comment requirements rules for which an Agency finds ''for good cause'' that notice and an opportunity to comment are ''impracticable, unnecessary, or contrary to the public interest.'' The Agency is invoking this exemption to address exigent public health issues associated with the Takata airbag recalls.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more 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. 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 action does not have substantial direct effects on one or more Indian tribes, on the relationship

between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Section 5–502 of Executive Order 13045 provides that in emergency situations, or where the Agency is required by law to act more quickly than normal review procedures allow, the Agency shall comply with the Executive Order to the extent practicable. This action is being issued under a good cause exemption of notice and comment rulemaking under the APA to address an emergency situation associated with defective airbag inflators and risks to public health. The rule will remove potential regulatory impediments associated with the Takata airbag recalls. The recalls address explosion risks associated with faulty airbag deployment which could cause (and have caused) serious harm to passengers in vehicles, including children.

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

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rulemaking simply removes potential regulatory impediments associated with the Takata airbag recalls; therefore, by itself, this rulemaking will not have any effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because the rule increases protection of human health and the environment by removing potential regulatory impediments associated with the Takata airbag recalls while ensuring safe management and disposal of airbag waste. The recalls address explosion risks associated with faulty airbag deployment which could cause (and have caused) serious harm to passengers, including passengers from minority and low-income communities.

M. Congressional Review Act

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section I.B. of this preamble, including the basis for that finding.

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Definitions, Hazardous waste.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Solid waste.

40 CFR Part 262

Environmental protection, Hazardous waste, Generator Standards.

Dated: November 13, 2018.

Andrew Wheeler,

Acting Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6935, 6937, 6938, 6939 and 6974.

Subpart B—Definitions

■ 2. Section 260.10 is amended by adding in alphabetical order definitions for ''Airbag waste'', ''Airbag waste collection facility'', and ''Airbag waste handler'' to read as follows:

§ 260.10 Definitions

* * * * *

Airbag waste means any hazardous waste airbag modules or hazardous waste airbag inflators.

Airbag waste collection facility means any facility that receives airbag waste from airbag handlers subject to regulation under § 261.4(j) of this chapter, and accumulates the waste for more than ten days.

Airbag waste handler means any person, by site, who generates airbag waste that is subject to regulation under this chapter.

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 3. The authority citation for Part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

Subpart A—General

■ 4. Section 261.4 is amended by adding reserved paragraph (i) and adding paragraph (j) to read as follows:

§ 261.4 Exclusions.

* * * * *

(j) *Airbag waste.* (1) Airbag waste at the airbag waste handler or during transport to an airbag waste collection facility or designated facility is not subject to regulation under parts 262 through 268, part 270, or part 124 of this chapter, and is not subject to the notification requirements of section 3010 of RCRA provided that:

(i) The airbag waste is accumulated in a quantity of no more than 250 airbag modules or airbag inflators, for no longer than 180 days;

(ii) The airbag waste is packaged in a container designed to address the risk posed by the airbag waste and labeled ''Airbag Waste–Do Not Reuse'';

(iii) The airbag waste is sent directly to either:

(A) An airbag waste collection facility in the United States under the control of a vehicle manufacturer or their authorized representative, or under the control of an authorized party administering a remedy program in response to a recall under the National Highway Traffic Safety Administration, or

(B) A designated facility as defined in 40 CFR 260.10;

(iv) The transport of the airbag waste complies with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 during transit;

(v) The airbag waste handler maintains at the handler facility for no less than three (3) years records of all off-site shipments of airbag waste and all confirmations of receipt from the receiving facility. For each shipment, these records must, at a minimum, contain the name of the transporter and date of the shipment; name and address of receiving facility; and the type and quantity of airbag waste (*i.e.,* airbag modules or airbag inflators) in the shipment. Confirmations of receipt must include the name and address of the

receiving facility; the type and quantity of the airbag waste (*i.e.,* airbag modules and airbag inflators) received; and the date which it was received. Shipping records and confirmations of receipt must be made available for inspection and may be satisfied by routine business records (*e.g.,* electronic or paper financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt).

(2) Once the airbag waste arrives at an airbag waste collection facility or designated facility, it becomes subject to all applicable hazardous waste regulations, and the facility receiving airbag waste is considered the hazardous waste generator for the purposes of the hazardous waste regulations and must comply with the requirements of 40 CFR part 262.

(3) Reuse in vehicles of defective airbag modules or defective airbag inflators subject to a recall under the National Highway Traffic Safety Administration is considered sham recycling and prohibited under 40 CFR 261.2(g).

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938 and 6939g.

Subpart A—General

■ 6. Section 262.14 is amended by revising paragraphs (a) introductory text and (a)(5) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) Provided that the very small quantity generator meets all the conditions for exemption listed in this section, hazardous waste generated by the very small quantity generator is not subject to the requirements of parts 124, 262 (except §§ 262.10 through 262.14) through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA and the very small quantity generator may accumulate hazardous waste on site without complying with such requirements. The conditions for exemption are as follows:

* * * * *

(5) A very small quantity generator that accumulates hazardous waste in amounts less than or equal to the limits in paragraphs (a)(3) and (4) of this section must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under part 270 of this chapter;

(ii) In interim status under parts 265 and 270 of this chapter;

(iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under part 271 of this chapter;

(iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to part 258 of this chapter;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in §§ 257.5 through 257.30 of this chapter;

(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;

(vii) For universal waste managed under part 273 of this chapter, a universal waste handler or destination facility subject to the requirements of part 273 of this chapter;

(viii) A large quantity generator under the control of the same person as the very small quantity generator, provided the following conditions are met:

(A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in § 260.10 of this chapter. ''Control,'' for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such generators.

(B) The very small quantity generator marks its container(s) of hazardous waste with:

(*1*) The words ''Hazardous Waste''; and

(*2*) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(ix)–(x) [Reserved]

(xi) For airbag waste, an airbag waste collection facility or a designated facility subject to the requirements of § 261.4(j) of this chapter.

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AB19

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule; effective date change.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' HHS published a final rule on January 5, 2017, that set forth the calculation of the 340B ceiling price and application of civil monetary penalties. On June 5, 2018, HHS published a final rule that delayed the effective date of the 340B ceiling price and civil monetary rule until July 1, 2019, to consider alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking. On November 2, 2018, HHS issued a proposed rule to solicit comments to change the effective date from July 1, 2019, to January 1, 2019, and to cease any further delay of the rule. HHS proposed this action because it determined that the January 5, 2017, final rule has been subject to extensive public comment, and had been delayed several times. HHS has considered the full range of comments on the substantive issues in the January 5, 2017, final rule. After consideration of the comments received on the effective date of the proposed rule, HHS is changing the effective date of the January 5, 2017, final rule, to January 1, 2019.

DATES: The effective date of the final rule published in the **Federal Register** on January 5, 2017, at 82 FR 1210, and delayed March 6, 2017 at 82 FR 12508, March 20, 2017 at 82 FR 14332, May 19, 2017 at 82 FR 22893, September 29,