conditional approval will automatically become a disapproval on that date and EPA will issue a finding of disapproval. EPA is not required to propose the finding of disapproval. If the conditional approval is converted to a disapproval, the final disapproval triggers the Federal Implementation Plan requirement under section 110(c). However, if the State meets its commitment within the applicable timeframe, the conditionally approved submission will remain a part of the SIP until EPA takes final action approving or disapproving the new submittal.

IV. Proposed Action

EPA is proposing to approve several SIP revisions submitted to EPA by the State of North Carolina, through NC DENR, to address the NO_X RACT requirements for the North Carolina portion of the bi-state Charlotte Area. Additionally, EPA is proposing to approve in part, and conditionally approve in part several SIP revisions to address the VOC RACT requirements and related CTG requirements. Specifically, North Carolina submitted SIP revisions on October 14, 2004, April 6, 2007, June 15, 2007, January 31, 2008, November 19, 2008, September 18, 2009, February 3, 2010, April 6, 2010, and November 9, 2010, to address NO_X RACT, VOC RACT and CTG requirements. Together, these SIP revisions establish the RACT requirements for the major sources located in the North Carolina portion of the bi-state Charlotte Area. In a separate rulemaking, EPA has already taken action on RACT and CTG requirements for the South Carolina portion of the bi-state Charlotte Area.

EPA has evaluated the proposed revisions to North Carolina's SIP, and has made the preliminary determination that they are consistent with statutory and regulatory requirements and EPA guidance except for the applicability for some CTG VOC sources. Consistent with section 110(k)(4) of the Act, EPA is relying upon a commitment by North Carolina to include appropriate applicability thresholds for VOC RACT for the all sources addressed by CTG in the Area as a basis for conditionally approving North Carolina's SIP revisions as they relate to VOC RACT.

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, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposal action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- 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 CAA; and
- Does not provide 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, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the determination does not have substantial direct effects on an Indian Tribe. There are no Indian Tribes located within the North Carolina portion of the bi-state Charlotte nonattainment area.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: March 5, 2013.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2013–05838 Filed 3–12–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2012–0111; FRL–9785–9]

RIN 2025–AA35

Addition of ortho-Nitrotoluene; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to add *ortho*-nitrotoluene (*o*-nitrotoluene) to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1990. *o*-Nitrotoluene has been classified by the National Toxicology Program in their 12th Report on Carcinogens as ''reasonably anticipated to be a human carcinogen.'' EPA believes that *o*-nitrotoluene meets the EPCRA section 313(d)(2)(B) criteria because it can reasonably be anticipated to cause cancer in humans. Based on a review of the available production and use information, *o*-nitrotoluene is expected to be manufactured, processed, or otherwise used in quantities that would exceed the EPCRA section 313 reporting thresholds.

DATES: Comments must be received on or before May 13, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–TRI–2012–0111, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: oei.docket@epa.gov*
- *Mail:* Office of Environmental Information (OEI) Docket, Environmental Protection Agency, Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–TRI–2012–

0111. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Environmental Analysis Division, Office of Information Analysis and Access (2842T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–566–0743; fax number: 202–566–0677; email: *bushman.daniel@epa.gov,* for specific information on this notice. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, toll free at (800) 424–9346 or (703) 412–9810 in Virginia and Alaska or toll free, TDD (800) 553–7672, *http://www.epa.gov/epaoswer/hotline/.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use *o*-nitrotoluene. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of potentially affected entities
Industry	Facilities included in the following NAICS manufacturing codes (corresponding to SIC codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 211112*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512220, 512230*, 519130*, 541712*, or 811490*. *Exceptions and/or limitations exist for these NAICS codes. Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (correspond to SIC 12, Coal Mining (except 1241)); or 212221, 212222, 212231, 212234, 212299 (correspond to SIC 10, Metal Mining (except 1011, 1081, and 1094)); or 221111, 221112, 221113, 221119, 221121, 221122, 221330 (Limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (correspond to SIC 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (Limited to facilities previously classified in SIC 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC 5171, Petroleum Bulk Terminals and Plants); or 562112 (Limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (Limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 et seq.) (correspond to SIC 4953, Refuse Systems).
Federal Government	Federal facilities

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Some of the entities listed in the table have exemptions and/or limitations regarding coverage, and other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How should I submit CBI to the agency?

Do not submit CBI information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

II. Introduction

Section 313 of EPCRA, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use

listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106. Congress established an initial list of toxic chemicals that comprised more than 300 chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if any of the listing criteria in Section 313(d)(2) are met. Therefore, to add a chemical, EPA must demonstrate that at least one criterion is met, but need not determine whether any other criterion is met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must demonstrate that none of the listing criteria in Section 313(d)(2) are met. The EPCRA section 313(d)(2) criteria are:

(A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

(B) The chemical is known to cause or can reasonably be anticipated to cause in humans–

(i) cancer or teratogenic effects, or

(ii) serious or irreversible—

(I) reproductive dysfunctions,

(II) neurological disorders,

(III) heritable genetic mutations, or

(IV) other chronic health effects.

(C) The chemical is known to cause or can be reasonably anticipated to cause, because of

(i) its toxicity,

(ii) its toxicity and persistence in the environment, or

(iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the section 313(d)(2)(A) criterion as the ''acute human health effects criterion;'' the section 313(d)(2)(B) criterion as the ''chronic human health effects criterion;'' and the section 313(d)(2)(C) criterion as the ''environmental effects criterion.''

EPA has published in the **Federal Register** of November 30, 1994 (59 FR 61432) a statement clarifying its interpretation of the section 313(d)(2) and (d)(3) criteria for modifying the section 313 list of toxic chemicals.

III. Background Information

A. What is the NTP and the report on Carcinogens?

The National Toxicology Program (NTP) is an interagency program within the Department of Health and Human Services (DHHS) headquartered at the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The mission of the NTP is to evaluate chemicals of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP program maintains an objective, science-based approach in dealing with critical issues in toxicology and is committed to using the best science available to prioritize, design, conduct, and interpret its studies. The mission of the NTP includes the evaluation of chemicals for their potential to cause cancer in humans.

As part of their cancer evaluation work, the NTP periodically publishes a Report on Carcinogens (RoC) document. The RoC was mandated by the U.S. Congress, as part of the Public Health Service Act (Section 301(b)(4), as amended). The NTP describes the RoC as an informational scientific and public health document that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a hazard to human health by virtue of their carcinogenicity. The NTP RoC serves as a meaningful and useful compilation of data on (1) the carcinogenicity (ability to cause cancer), genotoxicity (ability to damage genes), and biologic mechanisms (modes of action in the body) of the RoC-listed substances in humans and/or in animals, (2) the potential for human exposure to these substances, and (3) the regulations and guidelines promulgated by Federal agencies to limit exposures to RoC-listed substances. The NTP RoC is published periodically, with the most recently published 12th RoC having been released on June 10, 2011. The 12th RoC contains the NTP cancer classifications from the most recent chemical evaluations as well as the classifications from previous versions of the RoC.

B. What are the NTP cancer classifications and criteria?

The NTP RoC classifies chemicals as either ''known to be a human carcinogen'' or ''reasonably anticipated to be a human carcinogen.'' The criteria that the NTP uses to list an agent, substance, mixture, or exposure circumstance under each classification in the RoC (Ref. 1) are as follows:

''*Known To Be Human Carcinogen:*

There is sufficient evidence of carcinogenicity from studies in humans*, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be Human Carcinogen:

There is limited evidence of carcinogenicity from studies in humans*, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

or

there is sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

or

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

*This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance

in question, which can be useful for evaluating whether a relevant cancer mechanism is operating in humans.''

The NTP classifications for the potential for a chemical to cause cancer are very similar to the EPCRA section 313(d)(2)(B) statutory criteria for listing a chemical on the list of toxic chemicals subject to reporting under EPCRA section 313: ''(B) The chemical is known to cause or can reasonably be anticipated to cause in humans—(i) cancer * * *'' The specific data used by the NTP to classify a chemical as ''Known To Be Human Carcinogen'' or ''Reasonably Anticipated To Be Human Carcinogen'' are consistent with data used by EPA to evaluate chemicals for their potential to cause cancer and classify chemicals as either ''Carcinogenic to Humans'' or ''Likely to Be Carcinogenic to Humans'' (Ref. 2).

C. What is the review process for the RoC?

Specific details of the nomination and review process for the development of the 12th RoC are described in the NTP Report on Carcinogens Review Process section of the 12th RoC (Ref. 1). In general, the RoC review process includes evaluations by scientists from the NTP, other Federal health research and regulatory agencies (including EPA), and nongovernmental institutions. The RoC review process includes external peer review and several opportunities for public comment. For the 12th RoC, during the entire nomination, selection, and review process there were four opportunities for public comment. For each candidate substance, an expert panel was convened to peer review the NTP background document prepared for each candidate substance. The NTP also asked the expert panels to (1) apply the RoC listing criteria to the relevant scientific evidence and make a recommendation regarding the listing status for the candidate substance and (2) to provide the scientific justification for that recommendation. For the 12th RoC, the next step was a review by the Interagency Scientific Review Group (which included an EPA representative) followed by a review by the NIEHS/NTP Scientific Review Group. After these reviews, the NTP prepared a draft substance profile for each candidate substance which was peer reviewed by the NTP Board of Scientific Counselors which then prepared and submitted a peer review report to the NTP. The NTP then drafted the 12th RoC and submitted it to the NTP Director for review. The Director distributed the draft 12th RoC to the NTP Executive Committee for consultation, review, and comment. After approval of the draft 12th RoC by the NTP Director, the final draft of the 12th RoC was prepared and was submitted to the Secretary, DHHS, for review and approval. Once approved, the Secretary submitted the 12th RoC to the U.S. Congress as a final document. The 12th RoC was released to the public on June 10, 2011.

IV. EPA's review of the 12th RoC

A. How did EPA select the NTP RoC chemical being proposed for addition?

The most recent version of the NTP RoC that EPA previously reviewed for possible additions to the EPCRA section 313 list was the 11th RoC (April 6, 2010, 75 FR 17333). Each new version of the RoC adds newly classified chemicals to the existing list. EPA's present review of the 12th RoC identified four newly listed chemicals that are not on or covered by the EPCRA section list (aristolochic acids, captafol, o-nitrotoluene, and riddelliine). Of the four chemicals, only *o*-nitrotoluene is commercially produced and thus would be an appropriate candidate for listing under EPCRA section 313 since no reports would be expected for the other chemicals.

Section 313(d)(2) of EPCRA provides EPA the discretion to add chemicals to the TRI list when there is sufficient evidence to establish any of the listing criteria. EPA can add a chemical that meets one criterion regardless of its production volume or whether any reports would be filed. But as in past chemical reviews (e.g., January 12, 1994, 59 FR 1788), EPA adopted a production volume screen for the development of this proposed rule to make sure that reports would be expected to be submitted for the chemicals proposed to be listed. If a chemical that did not meet the production volume screen was listed, there would be an economic burden for firms that would have to determine that they did not exceed the reporting threshold. Yet, as no reports would be filed, there would be no information to the public on such a chemical. EPA feels it is appropriate at this time to focus on chemicals for which reports are likely to be filed.

EPA reviewed the NTP 12th RoC chemical profile and supporting materials for *o*-nitrotoluene (Ref. 3). Given the extensive scientific reviews conducted by the NTP for their RoC documents, EPA's review focused on ensuring that there were no inconsistencies with how the Agency would consider the available data. EPA's review of the *o*-nitrotoluene chemical profile and supporting material found no inconsistencies between how the data were interpreted by the NTP and how that same data would be interpreted under EPA's Guidelines for Carcinogen Risk Assessment (Ref. 2). Therefore, EPA agrees with the hazard conclusions of the NTP 12th RoC for *o*-nitrotoluene.

B. What technical data supports the NTP RoC classification and EPA's proposed addition of o-nitrotoluene to the EPCRA section 313 list?

This section presents the data that supported the NTP 12th RoC classification of *o*-nitrotoluene and why EPA believes the data support the addition of this chemical to the EPCRA section 313 list. The NTP chemical profile, the NTP chemical background document, and the references cited within the portion of the NTP 12th RoC chemical profile quoted here, are all included in the docket for this rulemaking. While they are contained in the docket and are part of the rulemaking record, the references within the quotation cited from the NTP 12th RoC profile document are not included in the list of references in Unit VI. of this **Federal Register** notice. The full citations for the references contained in the quotation can be found in the NTP 12th RoC profile document (Ref. 4).

1. o-Nitrotoluene (CAS No. 88–72–2) (Refs. NTP Profile/Background document (Refs. 4 and 5)). The NTP has classified *o*-nitrotoluene as ''reasonably anticipated to be a human carcinogen.'' The classification is based on sufficient evidence of carcinogenicity in experimental animals and supporting data on mechanisms of carcinogenesis. The NTP substance profile for o-nitrotoluene (Ref. 4) included the following summary information of the evidence of carcinogenicity:

''Carcinogenicity

o-Nitrotoluene is reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals and supporting data on mechanisms of carcinogenesis.

Cancer Studies in Experimental Animals

Oral exposure to *o*-nitrotoluene caused tumors at several different tissue sites in rats and mice and early onset of cancer in male rats. Malignant mesothelioma and mesothelial-cell hyperplasia of the tunica vaginalis of the epididymis were observed in male rats administered *o*-nitrotoluene in their feed for 13 weeks (NTP 1992). Bile-duct cancer (cholangiocarcinoma) was observed after 26 weeks, both in rats

exposed to *o*-nitrotoluene for 26 weeks and in rats exposed for 13 weeks and then observed for 13 more weeks without exposure (NTP 1996). *o*-Nitrotoluene caused cancer at several tissue sites in two-year chronic exposure studies of rats and mice of both sexes and in a study in which male rats were exposed to *o*-nitrotoluene for 13 weeks and evaluated at two years (NTP 2002). In rats, *o*-nitrotoluene caused (1) subcutaneous skin tumors and mammary-gland tumors (fibroadenoma) in both sexes, (2) malignant mesothelioma and benign or malignant tumors of the liver (hepatocellular adenoma or carcinoma or cholangiocarcinoma) and lung (alveolar/bronchiolar adenoma or carcinoma) in males, and (3) benign liver tumors (hepatocellular adenoma) in females. In mice, it caused malignant blood-vessel tumors (hemangiosarcoma) in both sexes, malignant tumors of the large intestine (cecal carcinoma) in males, and benign or malignant liver tumors (hepatocellular adenoma or carcinoma) in females (NTP 2002).

Studies on Mechanisms of Carcinogenesis

Following oral administration to rats and mice, *o*-nitrotoluene is absorbed into the blood and rapidly cleared; the serum half-life is 1.5 hours in rats (NTP 2002). In the rat liver, *o*-nitrotoluene is metabolized to *o*-nitrobenzyl alcohol and can follow several metabolic pathways: (1) glucuronidation to *o*-nitrobenzyl glucuronide, (2) sulfation and subsequent reaction with glutathione and acetylcysteine to *o*-nitrobenzyl sulfate, *S*-(o-nitrobenzyl)glutathione, and *S*-(*o*-nitrobenzyl)-*N*-acetylcysteine, or (3) metabolism to *o*-aminobenzyl alcohol followed by oxidation to *o*-aminobenzoic acid. The metabolites are eliminated primarily in the urine. The major metabolites are *o*-nitrobenzyl glucuronide and *o*-nitrobenzoic acid major metabolites in rats and mice and *o*-aminobenzyl alcohol and *S*-(*o*-nitrobenzyl)-*N*-acetylcysteine in rats. Female rats excrete less than half as much of the dose in the form of *o*-aminobenzyl alcohol, *o*-nitrobenzyl alcohol, or *S*-(*o*-nitrobenzyl)-*N*-acetylcysteine as male rats (NTP 2002). The glucuronidated form can also be excreted in the bile; when the glucuronidated form in the bile is excreted into the small intestine, intestinal bacteria can deconjugate it and reduce the nitro group to an amino group, forming aminobenzyl alcohol. Aminobenzyl alcohol can be reabsorbed from the intestine and further metabolized by the liver to reactive compounds (carbonium and nitrenium ions) that can covalently bind to DNA or to proteins (Chism and Rickert 1985, NTP 2002, 2008). Thus, microbial metabolism in the intestine is an important step in the carcinogenicity of *o*-nitrotoluene. However, neither *o*-aminobenzyl alcohol nor its metabolites have been detected in mouse urine after exposure to *o*-nitrotoluene (NTP 2002); therefore, other unidentified biochemical pathways leading to tumor formation most likely are involved.

o-Nitrotoluene did not cause mutations in bacteria. In studies of its ability to cause genetic damage in cultured mammalian cells, the results were mixed. *o*-Nitrotoluene caused (1) sister chromatid exchange in Chinese hamster ovary (CHO) cells, (2) chromosomal aberrations in Chinese hamster lung (CHL) cells and human peripheral lymphocytes but not in CHO cells, (3) micronucleus formation in CHL cells but not in CHO–K1 cells, and (4) DNA damage in L5178Y mouse lymphoma cells (NTP 2008). It did not induce DNA repair in rat or human hepatocytes (NTP 2008). In rats and mice exposed *in vivo, o*-nitrotoluene caused a slight increase in micronucleus formation in peripheral normochromatic erythrocytes in male mice at a high dose level; this finding was not considered conclusive. *o*-Nitrotoluene did not induce micronucleus formation in peripheral normochromatic erythrocytes in female mice or in polychromatic erythrocytes in the bone marrow of male rats or mice (NTP 2002). Following *in vivo* exposure of rats to *o*-nitrotoluene, DNA repair was increased in liver cells isolated from males, but not from females or germ-free males. These results, together with *o*-nitrotoluene's inability to induce DNA repair in hepatocytes *in vitro,* suggest that activation of *o*-nitrotoluene to become genotoxic is sex-specific and depends on both mammalian metabolism and metabolism by intestinal bacteria (Doolittle *et al.* 1983). However, *o*-nitrotoluene also caused tumors in other tissues in rats and mice of both sexes, suggesting that other activation mechanisms exist.

In rats exposed to *o*-nitrotoluene *in vivo,* DNA adducts were detected in the liver of males but not females (NTP 2008). Formation of DNA adducts was consistent with the reaction of intermediate compounds derived from *o*-aminobenzyl alcohol with guanine or adenine bases (Jones *et al.* 2003). The pattern of mutations in oncogenes from *o*-nitrotoluene-induced tumors was also consistent with guanine adduct formation: the majority of *p53* mutations in hemangiosarcomas were G:C to A:T transitions, and almost all the K-*ras* mutations in cecal carcinomas were G:C to T:A transversions (Hong *et al.* 2003, Sills *et al.* 2004). Mutations in the *p53,* β-*catenin,* and K-*ras* genes also were found in hemangiosarcomas from mice exposed to *o*-nitrotoluene, but not in spontaneously occurring hemangiosarcomas from unexposed mice (Hong *et al.* 2003).

In factory workers exposed to *o*-nitrotoluene, *o*-nitrotoluene–hemoglobin adducts were detected in the blood (Jones *et al.* 2005a), and *o*-nitrobenzoic acid and *o*-nitrobenzyl alcohol were detected in the urine (Jones *et al.* 2005b), providing evidence that human exposure to *o*-nitrotoluene results in production of a reactive metabolite(s). In addition, adducts between hemoglobin and 2-methylaniline (a metabolite of *o*-nitrotoluene) were identified in both exposed workers and exposed rats, and the level of 2-methylaniline–hemoglobin adducts in the blood of rats was proportional to the level of 2-methylaniline–DNA adducts in the livers of rats (Jones and Sabbioni 2003, Jones *et al.* 2003).

Cancer Studies in Humans

The data available from epidemiological studies are inadequate to evaluate the relationship between human cancer and exposure specifically to *o*-nitrotoluene. One cohort study of workers involved in the manufacture of magenta dye mentioned exposure of workers to *o*-nitrotoluene as part of the manufacturing process. A large excess of bladder cancer was reported; however, the workers were also exposed to other chemicals—*o*-toluidine (2-methylaniline) and 4,4′-methylenebis(2-methylaniline)—that are suspected of causing bladder cancer (Rubino *et al.* 1982). Two other studies of magenta manufacturing workers also reported an excess of bladder cancer, but did not report whether the workers were exposed to *o*-nitrotoluene (Case and Pearson 1954, Vineis and Magnani 1985).''

EPA has reviewed the NTP assessment for *o*-nitrotoluene and agrees that *o*-nitrotoluene can reasonably be anticipated to cause cancer in humans. EPA believes that the evidence is sufficient for listing *o*-nitrotoluene on EPCRA section 313 pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for this chemical.

V. Rationale for listing

The NTP RoC document undergoes significant scientific review and public comment. The NTP review mirrors the

review EPA has historically done to assess chemicals for listing under EPCRA section 313 on the basis of carcinogenicity. The conclusions regarding the potential for chemicals in the NTP RoC to cause cancer in humans are based on established sound scientific principles. EPA believes that the NTP RoC is an excellent and reliable source of information on the potential for chemicals covered in the NTP RoC to cause cancer in humans (see Unit III). Based on EPA's review of the data contained in the 12th NTP RoC, EPA has determined that *o*-nitrotoluene can reasonably be anticipated to cause cancer (Ref. 3). Therefore, EPA believes that the evidence is sufficient for listing *o*-nitrotoluene on the EPCRA section 313 toxic chemical list pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data presented in the 12th RoC.

EPA considers chemicals that can reasonably be anticipated to cause cancer to have moderately high to high chronic toxicity. EPA does not believe that it is appropriate to consider exposure for chemicals that are moderately high to highly toxic based on a hazard assessment when determining if a chemical can be added for chronic effects pursuant to EPCRA section 313(d)(2)(B) (*see* 59 FR 61440–61442). Therefore, in accordance with EPA's standard policy on the use of exposure assessments (59 FR 61432), EPA does not believe that an exposure assessment is necessary or appropriate for determining whether *o*-nitrotoluene meets the criteria of EPCRA section 313(d)(2)(B).

VI. References

EPA has established an official public docket for this action under Docket ID No. EPA–HQ–TRI–2012–0111. The public docket includes information considered by EPA in developing this action, including the documents listed below, which are electronically or physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are electronically or physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not electronically or physically located in the docket, please consult the person listed in the above **FOR FURTHER INFORMATION CONTACT** section.

1. NTP, 2011. National Toxicology Program. Report on Carcinogens, Twelfth Edition. Released June 10, 2011. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, Research Triangle Park, NC 27709.

2. USEPA. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC, March 2005.

3. USEPA, OEI. Memorandum from Martin Gehlhaus, Toxicologist, Analytical Support Branch to Larry Reisman, Chief, Analytical Support Branch. June 30, 2011. Subject: Review of National Toxicology Program (NTP) Cancer Classification Data for o-nitrotoluene.

4. NTP, 2011. National Toxicology Program. 12th Report on Carcinogens—o-Nitrotoluene Substance Profile. Released June 10, 2011. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, Research Triangle Park, NC 27709.

5. NTP, 2008. Report on Carcinogens Background Document for o-Nitrotoluene. June 20, 2008. U.S. Department of Health and Human Services, Public Health Services, National Toxicology Program, Research Triangle Park, NC 27709.

6. USEPA, OEI. Economic Analysis of the Proposed Rule to add *ortho*-Nitrotoluene to the EPCRA Section 313 List of Toxic Chemicals. February 9, 2012.

VII. What are the Statutory and Executive Order reviews associated with this action?

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'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This proposed rule does not contain any new information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et. seq. Currently, the facilities subject to the reporting requirements under EPCRA 313 and PPA 6607 may use either the EPA Toxic Chemicals Release Inventory Form R (EPA Form 1B9350–1), or the EPA Toxic Chemicals Release Inventory Form A (EPA Form 1B9350–2). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria. For the Form A, EPA established an alternative threshold for facilities with low annual reportable amounts of a listed toxic chemical. A facility that meets the appropriate reporting thresholds, but estimates that the total annual reportable amount of the chemical does not exceed 500 pounds per year, can take advantage of an alternative manufacture, process, or otherwise use threshold of 1 million pounds per year of the chemical, provided that certain conditions are met, and submit the Form A instead of the Form R. In addition, respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322 42 U.S.C. 11042: 40 CFR part 350.

OMB has approved the reporting and recordkeeping requirements related to Forms A and R, supplier notification, and petitions under OMB Control number 2025–0009 (EPA Information Collection Request (ICR) No. 1363) and those related to trade secret designations under OMB Control 2050–0078 (EPA ICR No. 1428). As provided in 5 CFR 1320.5(b) and 1320.6(a), 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 relevant to EPA's regulations are listed in 40 CFR part 9, 48 CFR chapter 15, and displayed on the information collection instruments (e.g., forms, instructions).

For the 17 Form Rs and 5 Form As expected to be filed, EPA estimates the industry reporting and recordkeeping burden for collecting this information to average, in the first year, $76,143 (based on 1,506 total burden hours). In subsequent years, the burden for collecting this information is estimated to average $36,252 (based on 717 total burden hours). These estimates include the time needed to become familiar with the requirement (first year only); review instructions; search existing data sources; gather and maintain the data needed; complete and review the collection information; and transmit or otherwise disclose the information. The actual burden on any facility may be different from this estimate depending on the complexity of the facility's operations and the profile of the releases at the facility. Upon promulgation of a final rule, the Agency may determine that the existing burden estimates in the ICRs need to be amended in order to account for an increase in burden associated with the final action. If so, the Agency will submit an information collection worksheet (ICW) to OMB requesting that the total burden in each ICR be amended, as appropriate.

The Agency would appreciate any comments or information that could be used to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including

whether the information will have practical utility; (2) evaluate the reasonableness of the Agency's estimate of the burden of the propose collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and, (4) 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. Please submit your comments within 90 days as specified at the beginning of this proposal. Copies of the existing ICRs may be obtained from Rick Westlund, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave. NW., Washington, DC 20460 or by calling (202) 566–1672.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A business that is classified as a ''small business'' by the Small Business Administration at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Of the 22 entities estimated to be impacted by this proposed rule, 6 are small businesses. Of the affected small businesses, all 6 have cost-to-revenue impacts of less than 1% in both the first and subsequent years of the rulemaking. No small businesses are projected to have a cost impact of the first year, of the 1% or greater. In 6 estimated cost impacts, there is a maximum impact of 0.204%. Facilities eligible to use Form A (those meeting the appropriate activity threshold which have 500 pounds per year or less of reportable amounts of the chemical) will have a lower burden. No small governments or small organizations are expected to be affected by this action. Thus this rule is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is located in EPA's economic analysis support document (Ref. 6). We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA's economic analysis indicates that the total cost of this rule is estimated to be $76,143 in the first year of reporting. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Small governments are not subject to the EPCRA section 313 reporting requirements.

E. 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, as specified in Executive Order 13132. This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Indian Tribal Governments, EPA specifically solicits additional comment on this proposed action from tribal officials.

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

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities.

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

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore,

EPA is not considering the use of any voluntary consensus standards.

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

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

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This proposed rule adds an additional chemical to the EPCRA section 313 reporting requirements. By adding a chemical to the list of toxic chemicals subject to reporting under section 313 of EPCRA, EPA would be providing communities across the United States (including minority populations and low income populations) with access to data which they may use to seek lower exposures and consequently reductions in chemical risks for themselves and their children. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the proposed rule will have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: March 5, 2013.

Bob Perciasepe,

Acting Administrator.

Therefore, it is proposed that 40 CFR part 372 be amended as follows:

PART 372—[AMENDED]

■ 1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

■ 2. Section 372.65 is amended by adding in the table of paragraph (a) ''o-Nitrotoluene'' in alphabetical order and adding in the table of paragraph (b) ''00088–72–2'' in numerical order to read as follows:

§ 372.65 Chemicals and chemical categories to which the part applies.

* * * * *

(a) * * *

Chemical name	CAS No.	Effective date
* * * * *	*	*
o-Nitrotoluene	00088–72–2	1/14
* * * * *	*	*

(b) * * *

CAS No.	Chemical name	Effective date
* * * * *	*	*
00088–72–2	o-Nitrotoluene	1/14
* * * * *	*	*

[FR Doc. 2013–05812 Filed 3–12–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2013–0030]

RIN 2127–AL24

Federal Motor Vehicle Safety Standards; Tire Selection and Rims

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to amend Federal Motor Vehicle Safety Standard (FMVSS) No. 110 to make it clear that special trailer (ST) tires are permitted to be installed on new trailers with a gross vehicle weight rating (GVWR) of 4,536 kg (10,000 lbs.) or less. It also proposes to exclude these trailers from a vehicle testing requirement that a tire must be retained on its rim when subjected to a sudden loss of tire pressure when brought to a controlled stop from 97 km/h (60 mph). After careful review, the agency believes that these two revisions are appropriate and would not result in any degradation of motor vehicle safety.

DATES: Submit comments on or before May 13, 2013.

ADDRESSES: You may submit comments electronically to the docket identified in the heading of this document by visiting the following Web site:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Alternatively, you can file comments using the following methods:

- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between