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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2015–0730; FRL–9956–21–OAR]

RIN 2060–AS93

National Emission Standards for Hazardous Air Pollutants: Nutritional Yeast Manufacturing Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Manufacturing of Nutritional Yeast source category. The proposed amendments address the results of the residual risk and technology reviews (RTRs) conducted as required under the Clean Air Act (CAA) as well as other actions deemed appropriate during the review of these standards. The proposed amendments include revising the form of the fermenter volatile organic compounds (VOC) emission limits, changing the testing and monitoring requirements, and updating the reporting and recordkeeping requirements.

DATES: *Comments.* Comments must be received on or before February 13, 2017. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before January 27, 2017.

Public Hearing. A public hearing will be held, if requested by January 3, 2017.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0730, at *http://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 *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Allison Costa, Sector Policies and Programs Division (Mail Code E140), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1322; fax number: (919) 541–3470; and email address: *costa.allison@epa.gov.* For specific information regarding the risk modeling methodology, contact Chris Sarsony, Health and Environmental Impacts Division (Mail Code C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4843; fax number: (919) 541–0840; and email address: *sarsony.chris@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Scott Throwe, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, EPA WJC South Building (Mail Code 2227A), 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (919) 564–7013; fax number: (202) 564–0050; and email address: *throwe.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2015–0730. All documents in the docket are listed in the *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, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *Regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room 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 EPA Docket Center is (202) 566–1742.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2015–0730. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means the 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 the EPA without going through *http://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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Public Hearing. A public hearing will be held, if requested by January 3, 2017, to accept oral comments on this proposed action. If a hearing is requested, it will be held at the EPA's North Carolina campus located at 109 T.W. Alexander Drive, Research Triangle Park, NC 27711. The hearing, if requested, will begin at 9:00 a.m. (local time) and will conclude at 8:00 p.m. (local time). To request a hearing, to register to speak at a hearing, or to inquire if a hearing will be held, please contact Aimee St. Clair at (919) 541–1063 or by email at *StClair.Aimee@epa.gov.* The last day to pre-register to speak at a hearing, if one is held, will be January 10, 2017. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk, although preferences on speaking times may not be able to be fulfilled. Please note that registration requests received before the hearing will be confirmed by the EPA via email. The EPA will make every effort to accommodate all speakers who arrive and register. Because the hearing will be held at a U.S. governmental facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. If your driver's license is issued by Alaska, American Samoa, Arizona, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Montana, New York, Oklahoma or the state of Washington, you must present an additional form of identification to enter the federal building. Acceptable alternative forms of identification include: federal employee badges, passports, enhanced driver's licenses and military identification cards. In addition, you will need to obtain a property pass for any personal belongings you bring with you. Upon leaving the building, you will be required to return this property pass to the security desk. No large signs will be allowed in the building, cameras may only be used outside of the building and demonstrations will not be allowed on federal property for security reasons.

Please note that any updates made to any aspect of the hearing, including whether or not a hearing will be held, will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.* We ask that you contact Aimee St. Clair at (919) 541–1063 or by email at *StClair.Aimee@epa.gov* or monitor our Web site to determine if a hearing will be held. The EPA does not intend to publish a notice in the **Federal Register** announcing any such updates. Please go to *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards* for more information on the public hearing.

Preamble Acronyms and Abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

AEGL	Acute exposure guideline levels
AERMOD	Air dispersion model used by the HEM–3 model
ATSDR	Agency for Toxic Substances and Disease Registry
CAA	Clean Air Act
CalEPA	California EPA
CBI	Confidential Business Information
CDX	Central Data Exchange
CEDRI	Compliance and Emissions Data Reporting Interface
CEMS	Continuous emission monitoring system
CFR	Code of Federal Regulations
EGU	Electric generation unit
EPA	Environmental Protection Agency
ERPG	Emergency Response Planning Guidelines
FR	Federal Register
HAP	Hazardous air pollutants
HCl	Hydrochloric acid
HEM–3	Human Exposure Model, Version 1.1.0
HF	Hydrogen fluoride
HI	Hazard index
HQ	Hazard quotient
ICR	Information Collection Request
IRIS	Integrated Risk Information System
km	Kilometer
MACT	Maximum achievable control technology
MATS	Mercury Air Toxics Standard
mg/kg-day	Milligrams per kilogram per day
mg/m^3	Milligrams per cubic meter
MIR	Maximum individual risk
MON	Miscellaneous organic chemical manufacturing NESHAP
NAAQS	National Ambient Air Quality Standards
NAICS	North American Industry Classification System
NAS	National Academy of Sciences
NATA	National Air Toxics Assessment
NEI	National Emissions Inventory
NESHAP	National emissions standards for hazardous air pollutants
NO_X	Nitrogen oxides
NRC	National Research Council
QA/QC	Quality assurance/quality control
OAQPS	Office of Air Quality Planning and Standards
OMB	Office of Management and Budget
PB–HAP	Hazardous air pollutants known to be persistent and bio-accumulative in the environment
POM	Polycyclic organic matter
ppmv	Parts per million by volume
PRA	Paperwork Reduction Act
PS	Performance Specification
RBLC	RACT/BACT/LAER Clearinghouse
REL	Reference exposure level
RFA	Regulatory Flexibility Act
RfC	Reference concentration
RfD	Reference dose
RTO	Regenerative thermal oxidizer
RTR	Residual risk and technology review
SAB	Science Advisory Board
SBA	Small Business Administration
SOP	Standing Operating Procedures
SSM	Startup, shutdown, and malfunction
TOSHI	Target organ-specific hazard index
tpy	Tons per year
TRIM.FaTE	Total Risk Integrated Methodology. Fate, Transport, and Ecological Exposure model
TTN	Technology Transfer Network
UF	Uncertainty factor
$\mu g/m^3$	Microgram per cubic meter
UMRA	Unfunded Mandates Reform Act
URE	Unit risk estimate
VOC	Volatile organic compounds

Organization of this Document. The information in this preamble is organized as follows:

I. General Information
  A. Does this action apply to me?
  B. Where can I get a copy of this document and other related information?
  C. What should I consider as I prepare my comments for the EPA?
II. Background
  A. What is the statutory authority for this action?
  B. What is this source category and how does the current NESHAP regulate its HAP emissions?
  C. What data collection activities were conducted to support this action?
  D. What other relevant background information and data are available?
III. Analytical Procedures
  A. How did we estimate post-MACT risks posed by the source category?
  B. How did we consider the risk results in making decisions for this proposal?
  C. How did we perform the technology review?
IV. Analytical Results and Proposed Decisions
  A. What are the results of the risk assessment and analyses?
  B. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effects?
  C. What are the results and proposed decisions based on our technology review?
  D. What other actions are we proposing?
  E. What compliance dates are we proposing?
V. Summary of Cost, Environmental, and Economic Impacts
  A. What are the affected sources?
  B. What are the air quality impacts?
  C. What are the cost impacts?
  D. What are the economic impacts?
  E. What are the benefits?
VI. Request for Comments
VII. Submitting Data Corrections
VIII. Statutory and Executive Order Reviews
  A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  B. Paperwork Reduction Act (PRA)
  C. Regulatory Flexibility Act (RFA)
  D. Unfunded Mandates Reform Act (UMRA)
  E. Executive Order 13132: Federalism
  F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
  G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
  H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
  I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR part 51
  J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and the associated regulated industrial source category that is the subject of this proposal. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (*see* 57 FR 31576, July 16, 1992), the Manufacturing of Nutritional Yeast source category includes any facility engaged in the manufacture of baker's yeast by fermentation (both active dry yeast and compressed yeast). The category includes, but is not limited to, the following manufacturing process units: fermentation vessels and the drying and packaging system. The original source category was named Baker's Yeast Manufacturing, but it was revised to Manufacturing of Nutritional Yeast to provide clarity on the scope (63 FR 55812, October 19, 1998).

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

NESHAP and source category	NAICS code [1]
Manufacturing of Nutritional Yeast	311999

[1] North American Industry Classification System (NAICS).

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same Web site. Information on the overall RTR program is available at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.*

C. What should I consider as I prepare my comments for the EPA?

Submitting CBI. Do not submit information containing CBI to the EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to the 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 comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI for inclusion in the public docket. If you submit a CD–ROM or disk that does not contain CBI, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2015–0730.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, after the EPA has identified categories of sources emitting one or more of the HAP listed in CAA section 112(b), CAA section 112(d) requires us to promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. For major sources, the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements and non-air quality health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards.

MACT standards must reflect the maximum degree of emissions reduction achievable through the application of measures, processes, methods, systems or techniques, including, but not limited to, measures that: (1) Reduce the volume of or eliminate pollutants through process changes, substitution of materials, or other modifications; (2) enclose systems or processes to eliminate emissions; (3) capture or treat pollutants when released from a process, stack, storage, or fugitive emissions point; (4) are design, equipment, work practice, or operational standards (including requirements for operator training or certification); or (5) are a combination of the above. CAA section 112(d)(2)(A)–(E). The MACT standards may take the form of design, equipment, work practice, or operational standards where the EPA first determines either that: (1) A pollutant cannot be emitted through a conveyance designed and constructed to emit or capture the pollutant, or that any requirement for, or use of, such a conveyance would be inconsistent with law; or (2) the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations. CAA section 112(h)(1)–(2).

The MACT ''floor'' is the minimum control level allowed for MACT standards promulgated under CAA section 112(d)(3) and may not be based on cost considerations. For new sources, the MACT floor cannot be less stringent than the emissions control that is achieved in practice by the best-controlled similar source. The MACT floor for existing sources can be less stringent than floors for new sources, but not less stringent than the average emissions limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, the EPA must also consider control options that are more stringent than the floor. We may establish standards more stringent than the floor based on considerations of the cost of achieving the emission reductions, any non-air quality health and environmental impacts, and energy requirements.

The EPA is then required to review these technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years. CAA section 112(d)(6). In conducting this review, the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council* (*NRDC*) v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers,* *Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013).

The second stage in standard-setting focuses on reducing any remaining (*i.e.,* ''residual'') risk according to CAA section 112(f). CAA section 112(f)(1) required that the EPA prepare a report to Congress discussing (among other things) methods of calculating the risks posed (or potentially posed) by sources after implementation of the MACT standards, the public health significance of those risks, and the EPA's recommendations as to legislation regarding such remaining risk. The EPA prepared and submitted the ''Residual Risk Report to Congress,'' EPA–453/R–99–001 (''Risk Report'') in March 1999. CAA section 112(f)(2) then provides that if Congress does not act on any recommendation in the Risk Report, the EPA must analyze and address residual risk for each category or subcategory of sources 8 years after promulgation of such standards pursuant to CAA section 112(d).

Section 112(f)(2) of the CAA requires the EPA to determine for source categories subject to MACT standards whether the emission standards provide an ample margin of safety to protect public health. Section 112(f)(2)(B) of the CAA expressly preserves the EPA's use of the two-step process for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and in a challenge to the risk review for the Synthetic Organic Chemical Manufacturing source category, the United States Court of Appeals for the District of Columbia Circuit upheld as reasonable the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. *See NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008)(''[S]ubsection 112(f)(2)(B) expressly incorporates the EPA's interpretation of the Clean Air Act from the Benzene standard, complete with a citation to the **Federal Register**.''); *see* also, *A Legislative History of the Clean Air Act Amendments of 1990,* vol. 1, p. 877 (Senate debate on Conference Report).

The first step in the process of evaluating residual risk is the determination of acceptable risk. If risks are unacceptable, the EPA cannot consider cost in identifying the emissions standards necessary to bring risks to an acceptable level. The second step is the determination of whether standards must be further revised in order to provide an ample margin of safety to protect public health. The ample margin of safety is the level at which the standards must be set, unless an even more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

1. Step 1—Determination of Acceptability

The Agency in the Benzene NESHAP concluded that ''the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information'' and that the ''judgment on acceptability cannot be reduced to any single factor.'' Benzene NESHAP at 38046. The determination of what represents an ''acceptable'' risk is based on a judgment of ''what risks are acceptable in the world in which we live'' (Risk Report at 178, quoting *NRDC* v. *EPA,* 824 F.2d 1146, 1165 (D.C. Cir. 1987) (en banc) (''Vinyl Chloride''), recognizing that our world is not risk-free.

In the Benzene NESHAP, we stated that ''EPA will generally presume that if the risk to [the maximum exposed] individual is no higher than approximately one in 10 thousand, that risk level is considered acceptable.'' 54 FR at 38045, September 14, 1989. We discussed the maximum individual lifetime cancer risk (or maximum individual risk (MIR)) as being ''the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years.'' *Id.* We explained that this measure of risk ''is an estimate of the upper bound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years.'' *Id.* We acknowledged that maximum individual lifetime cancer risk ''does not necessarily reflect the true risk, but displays a conservative risk level which is an upper-bound that is unlikely to be exceeded.'' *Id.*

Understanding that there are both benefits and limitations to using the MIR as a metric for determining acceptability, we acknowledged in the Benzene NESHAP that ''consideration of maximum individual risk * * * must take into account the strengths and weaknesses of this measure of risk.'' *Id.* Consequently, the presumptive risk level of 100-in-1 million (1-in-10 thousand) provides a benchmark for judging the acceptability of maximum individual lifetime cancer risk, but does not constitute a rigid line for making that determination. Further, in the Benzene NESHAP, we noted that:

> ''[p]articular attention will also be accorded to the weight of evidence presented in the risk assessment of potential carcinogenicity or other health effects of a pollutant. While the same numerical risk may be estimated for an exposure to a pollutant judged to be a known human carcinogen, and to a pollutant considered a possible human carcinogen based on limited animal test data, the same weight cannot be accorded to both estimates. In considering the potential public health effects of the two pollutants, the Agency's judgment on acceptability, including the MIR, will be influenced by the greater weight of evidence for the known human carcinogen.''

Id. at 38046. The Agency also explained in the Benzene NESHAP that:

> ''[i]n establishing a presumption for MIR, rather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 kilometers (km) exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants.''

Id. at 38045. In some cases, these health measures and factors taken together may provide a more realistic description of the magnitude of risk in the exposed population than that provided by maximum individual lifetime cancer risk alone.

As noted earlier, in *NRDC* v. *EPA,* the Court held that CAA section 112(f)(2) ''incorporates the EPA's interpretation of the Clean Air Act from the Benzene Standard.'' The Court further held that Congress' incorporation of the Benzene standard applies equally to carcinogens and non-carcinogens. 529 F.3d at 1081–82. Accordingly, we also consider non-cancer risk metrics in our determination of risk acceptability and ample margin of safety.

2. Step 2—Determination of Ample Margin of Safety

CAA section 112(f)(2) requires the EPA to determine, for source categories subject to MACT standards, whether those standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, ''the second step of the inquiry, determining an 'ample margin of safety,' again includes consideration of all of the health factors, and whether to reduce the risks even further. . . . Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by section 112.'' 54 FR 38046, September 14, 1989.

According to CAA section 112(f)(2)(A), if the MACT standards for HAP ''classified as a known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million,'' the EPA must promulgate residual risk standards for the source category (or subcategory), as necessary to provide an ample margin of safety to protect public health. In doing so, the EPA may adopt standards equal to existing MACT standards if the EPA determines that the existing standards (*i.e.,* the MACT standards) are sufficiently protective. *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'') The EPA must also adopt more stringent standards, if necessary, to prevent an adverse environmental effect,[1] but must consider cost, energy, safety, and other relevant factors in doing so.

The CAA does not specifically define the terms ''individual most exposed,'' ''acceptable level,'' and ''ample margin of safety.'' In the Benzene NESHAP, 54 FR 38044, September 14, 1989, we stated as an overall objective:

> In protecting public health with an ample margin of safety under section 112, EPA strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1-in-1 million and (2) limiting to no higher than approximately 1-in-10 thousand [*i.e.,* 100-in-1 million] the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years.

The Agency further stated that ''[t]he EPA also considers incidence (the number of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risks to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other serious health effects in the exposed population.'' *Id.* at 38045.

In the ample margin of safety decision process, the Agency again considers all of the health risks and other health information considered in the first step, including the incremental risk reduction associated with standards more stringent than the MACT standard or a more stringent standard that the EPA has determined is necessary to ensure risk is acceptable. In the ample margin of safety analysis, the Agency considers additional factors, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by CAA section 112(f). 54 FR 38046, September 14, 1989.

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

In the original 1992 list of sources under CAA section 112(c)(1), the EPA defined the Baker's Yeast Manufacturing source category as including any facility engaged in the manufacture of baker's yeast by fermentation (both active dry yeast and compressed yeast) (57 FR 31576). The EPA explained that the category included, but was not limited to, the following manufacturing process units: Fermentation vessels and the drying and packaging system. The original source category was renamed to Manufacturing of Nutritional Yeast in 1998 to clarify that the source category covered the manufacturing of yeast, not its use in facilities such as breweries or bakeries. Both ''baker's yeast'' and ''nutritional yeast'' are common names for *Saccharomyces cerevisiae,* which is a specific species of yeast that is used to produce many common food and beverage products and whose manufacturing process typically emits HAP. The 40 CFR part 63, subpart CCCC NESHAP, which was finalized in 2001, defines a manufacturer of nutritional yeast as a facility that makes yeast for the purpose of becoming an ingredient in dough for bread or any other yeast-raised baked product, or for becoming a nutritional food additive intended for consumption by humans (66 FR 27876). Facilities that manufacture nutritional yeast intended for consumption by animals, such as an additive for livestock feed, are not included in the description of sources covered by this subpart in 40 CFR 63.2131. In addition, the NESHAP clarifies that fermenters are not subject to emission limits during the production of specialty yeast (*e.g.,* yeast for use in wine, champagne, whiskey, or beer) in 40 CFR 63.2132. We are not proposing to amend the source category definition in this action and are, therefore, not seeking comment on the source category definition at this time.

Only facilities that are located at or are part of a major source of HAP emissions are subject to the Manufacturing of Nutritional Yeast NESHAP; area sources of HAP are not subject to the rule. The HAP emitted by nutritional yeast manufacturing facilities is acetaldehyde, a probable carcinogen. In 2016, there are four nutritional yeast manufacturing facilities that are subject to the NESHAP.

The affected sources at nutritional yeast manufacturing facilities are the collection of equipment used to manufacture *Saccharomyces cerevisiae* yeast, including fermenters. The sizes of the fermenters vary; generally smaller fermenters are used for earlier fermentation stages and larger fermenters are used for later fermentation stages. The initial, smaller fermenters, where the sugar source is added only at the start of the batch (*e.g.,* laboratory and pure culture fermenters), are not subject to emission limits. The 40 CFR part 63, subpart CCCC emission limits apply to the final three stages of the fermentation process where the sugar source is added intermittently throughout the process, which are often referred to as stock (third-to-last stage), first generation (second-to-last stage), and trade (last stage) fermentation.

Currently, the fermenters are subject to batch average VOC emission limits that differ for each fermentation stage, and which must be met for 98 percent of all batches in each fermentation stage on a rolling 12-month basis. VOC is used as a surrogate for the HAP of interest, acetaldehyde. The batch

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[1] ''Adverse environmental effect'' is defined as any significant and widespread adverse effect, which may be reasonably anticipated to wildlife, aquatic life, or natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental qualities over broad areas. CAA section 112(a)(7).

average VOC limits are 300 parts per million by volume (ppmv) for stock fermenters (third-to-last stage), 200 ppmv for first generation fermenters (second-to-last stage), and 100 ppmv for trade fermenters (last stage).

In the current NESHAP, facilities can continuously monitor either the VOC concentration in the fermenter exhaust or the brew ethanol concentration in the fermenter liquid to determine compliance with the emission limits. If a facility monitors brew ethanol concentration, it must conduct an annual performance test to determine the correlation between the brew ethanol concentration in the fermenter liquid and the VOC concentration in the fermenter exhaust gas.

C. What data collection activities were conducted to support this action?

The EPA visited three nutritional yeast manufacturing facilities during the development of the NESHAP. Those facilities were the American Yeast and AB Mauri Fleischmann's Yeast facilities in Memphis, Tennessee, which we visited in December 2015, and the Red Star Yeast facility in Cedar Rapids, Iowa, which we visited in June 2016. We also held a conference call with the Minn-Dak Wahpeton facility, located in Wahpeton, North Dakota, in May 2016. The EPA discussed the specific yeast fermentation processes employed by each facility, including a discussion of the number and design of their fermenters and associated emission points, the process controls and monitors used, unregulated emission sources, and other aspects of facility operations. The site visits and conference call are documented in separate memoranda: ''Site Visit Report—American Yeast Corporation, Memphis Plant,'' ''Site Visit Report—AB Mauri Fleischmann's Yeast, Memphis Plant,'' ''Site Visit Report—Red Star Yeast, Cedar Rapids, IA,'' and ''Notes from May 6, 2016 Conference Call Between the EPA and Minn-Dak Wahpeton,'' which are available in the docket for this action.

D. What other relevant background information and data are available?

The EPA used information from the National Emissions Inventory (NEI) and the RACT/BACT/LAER Clearinghouse (RBLC) to support this proposed rulemaking. We used the NEI emissions and supporting data to develop the modeling file for the risk review. The EPA utilized the RBLC to identify additional control technologies for the technology review. See sections III.A, III.C, and IV.C of this preamble for further details on the use of these sources of information.

III. Analytical Procedures

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this proposal.

A. How did we estimate post-MACT risks posed by the source category?

The EPA conducted a risk assessment that provides estimates of the MIR posed by the HAP emissions from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause non-cancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause non-cancer health effects. The assessment also provides estimates of the distribution of cancer risks within the exposed populations, cancer incidence, and an evaluation of the potential for adverse environmental effects. The eight sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule.'' The methods used to assess risks (as described in the eight primary steps below) are consistent with those peer-reviewed by a panel of the EPA's Science Advisory Board (SAB) in 2009 and described in their peer review report issued in 2010;[2] they are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

Fermenters are the primary emission source at nutritional yeast facilities. Each fermenter emission source has a stack through which the emissions are vented. The HAP emitted is acetaldehyde, which is a by-product of the fermentation process. We used acetaldehyde emissions data from the 2011 NEI and state emission reports (*i.e.,* Iowa Emissions Inventory Questionnaire reports) as the basis of the actual emission estimates for each facility. The stack parameters used for each fermenter were obtained from the 2011 NEI, title V permits, or were provided to the Agency during site visits. We used default parameters if site-specific information was not available. Additional details on the data and methods used to develop actual emissions for the risk modeling are provided in the memorandum, ''Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during the specified annual time period. In some cases, these ''actual'' emission levels are lower than the emission levels required to comply with the current MACT standards. The emissions level allowed to be emitted by the MACT standards is referred to as the ''MACT-allowable'' emissions level. We discussed the use of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19998–19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTRs (71 FR 34428, June 14, 2006, and 71 FR 76609, December 21, 2006, respectively). In those actions, we noted that assessing the risks at the MACT-allowable level is inherently reasonable since these risks reflect the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach. (54 FR 38044, September 14, 1989.)

For nutritional yeast manufacturing facilities, we used the actual emissions as the basis for the MACT-allowable emissions in the risk assessment. We set allowable emissions equal to actual emissions based on information gathered during the site visits that the facilities are operating near maximum capacity and close to the level of emissions allowed under the NESHAP. It is difficult to calculate a precise allowable emissions level for this industry because the emission limits are based on the average emissions concentration during each batch and the absolute number of batches produced at a facility fluctuates each year based on market demand for yeast.

Furthermore, facilities are also unlikely to emit significantly higher levels of HAP due to a business incentive to minimize acetaldehyde

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[2] U.S. EPA SAB. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing,* May 2010.

emissions and continuous monitoring requirements in the rule. Acetaldehyde is a by-product of sub-optimal yeast production. Increasing concentrations of acetaldehyde indicate decreases relative to the potential amount and/or quality of yeast that can be produced within a fermentation batch, resulting in a loss of profit for the yeast manufacturer. Therefore, companies have a business incentive to reduce HAP emissions as much as possible. Additionally, continuous monitoring ensures that the facilities receive real-time information about emissions throughout the yeast manufacturing process. These monitoring systems have enabled facilities to set up control systems that automatically adjust process parameters in real-time to reduce emissions if they reach a specified level.

As stated above, MACT-allowable emissions are used to develop estimates of risk when actual emissions are lower than those required to meet current emission standards. Due to the difficulties that limit the calculation of allowable emissions (*e.g.,* the current NESHAP standard requirements) and the low likelihood of facilities emitting significantly higher levels of HAP than current amounts, actual emissions provide the most accurate estimate of emissions that will be emitted from nutritional yeast manufacturing facilities. Therefore, we determined that the use of actual emissions as the basis of the MACT-allowable emissions in this risk assessment is the most appropriate option for this subpart.

3. How did we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risks?

Both long-term and short-term inhalation exposure concentrations and health risks from the source category addressed in this proposal were estimated using the Human Exposure Model (Community and Sector HEM–3 version 1.1.0). The HEM–3 performs three primary risk assessment activities: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 km of the modeled sources,[3] and (3) estimating individual and population-level inhalation risks using the exposure estimates and quantitative dose-response information.

The air dispersion model used by the HEM–3 model (AERMOD) is one of the EPA's preferred models for assessing pollutant concentrations from industrial facilities.[4] To perform the dispersion modeling and to develop the preliminary risk estimates, HEM–3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2014) of hourly surface and upper air observations for more than 800 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block[5] internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant unit risk factors and other health benchmarks is used to estimate health risks. These risk factors and health benchmarks are the latest values recommended by the EPA for HAP and other toxic air pollutants. These values are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants* and are discussed in more detail later in this section.

In developing the risk assessment for chronic exposures, we used the estimated annual average ambient air concentrations of each HAP emitted by each source for which we have emissions data in the source category. The air concentrations at each nearby census block centroid were used as a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. We calculated the MIR for each facility as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, and 52 weeks per year for a 70-year period) exposure to the maximum concentration at the centroid of inhabited census blocks. Individual cancer risks were calculated by multiplying the estimated lifetime exposure to the ambient concentration of each of the HAP (in micrograms per cubic meter ($\mu g/m^3$)) by its unit risk estimate (URE). The URE is an upper bound estimate of an individual's probability of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use URE values from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) URE values, where available. In cases where new, scientifically credible dose response values have been developed in a manner consistent with the EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate.

The EPA estimated incremental individual lifetime cancer risks associated with emissions from the facilities in the source category as the sum of the risks for each of the carcinogenic HAP (including those classified as carcinogenic to humans, likely to be carcinogenic to humans, and suggestive evidence of carcinogenic potential)[6] emitted by the modeled sources. Cancer incidence and the distribution of individual cancer risks for the population within 50 km of the sources were also estimated for the source category as part of this assessment by summing individual risks. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044, September 14, 1989) and the limitations of Gaussian dispersion models, including AERMOD.

To assess the risk of non-cancer health effects from chronic exposures, we summed the HQ for each of the HAP that affects a common target organ system to obtain the HI for that target organ system (or target organ-specific HI, TOSHI). The HQ is the estimated exposure divided by the chronic reference value, which is a value selected from one of several sources. First, the chronic reference level can be the EPA reference concentration (RfC) (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=Risk*

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[3] This metric comes from the Benzene NESHAP. See 54 FR 38046.

[4] U.S. EPA. Revision to the ''Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions'' (70 FR 68218, November 9, 2005).

[5] A census block is the smallest geographic area for which census statistics are tabulated.

[6] These classifications also coincide with the terms ''known carcinogen, probable carcinogen, and possible carcinogen,'' respectively, which are the terms advocated in the EPA's previous ''Guidelines for Carcinogen Risk Assessment,'' published in 1986 (51 FR 33992, September 24, 1986). Summing the risks of these individual compounds to obtain the cumulative cancer risks is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled, ''NATA—Evaluating the National-scale Air Toxics Assessment 1996 Data—an SAB Advisory,'' available at *http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf.*

%20Assessment%20Glossary), defined as ''an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.'' Alternatively, in cases where an RfC from the EPA's IRIS database is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic reference level can be a value from the following prioritized sources: (1) The Agency for Toxic Substances and Disease Registry Minimum Risk Level (*http://www.atsdr.cdc.gov/mrls/index.asp*), which is defined as ''an estimate of daily human exposure to a hazardous substance that is likely to be without an appreciable risk of adverse non-cancer health effects (other than cancer) over a specified duration of exposure''; (2) the CalEPA Chronic Reference Exposure Level (REL) (*http://oehha.ca.gov/media/downloads/crnr/2015guidance manual.pdf*), which is defined as ''the concentration level (that is expressed in units of micrograms per cubic meter (μg/m^3) for inhalation exposure and in a dose expressed in units of milligram per kilogram-day (mg/kg-day) for oral exposures), at or below which no adverse health effects are anticipated for a specified exposure duration''; or (3), as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with the EPA guidelines and has undergone a peer review process similar to that used by the EPA, in place of or in concert with other values.

As mentioned above, in order to characterize non-cancer chronic effects, and in response to key recommendations from the SAB, the EPA selects dose-response values that reflect the best available science for all HAP included in RTR risk assessments.[7] More specifically, for a given HAP, the EPA examines the availability of inhalation reference values from the sources included in our tiered approach (*e.g.,* IRIS first, Agency for Toxic Substances and Disease Registry (ATSDR) second, CalEPA third) and determines which inhalation reference value represents the best available science. Thus, as new inhalation reference values become available, the EPA will typically evaluate them and determine whether they should be given preference over those currently being used in RTR risk assessments.

The EPA also evaluated screening estimates of acute exposures and risks for each of the HAP (for which appropriate acute dose-response values are available) at the point of highest potential off-site exposure for each facility. To do this, the EPA estimated the risks when both the peak hourly emissions rate and worst-case dispersion conditions occur. We also assume that a person is located at the point of highest impact during that same time. In accordance with our mandate in section 112 of the CAA, we use the point of highest off-site exposure to assess the potential risk to the maximally exposed individual. The acute HQ is the estimated acute exposure divided by the acute dose-response value. In each case, the EPA calculated acute HQ values using best available, short-term dose-response values. These acute dose-response values, which are described below, include the acute REL, acute exposure guideline levels (AEGL) and emergency response planning guidelines (ERPG) for 1-hour exposure durations. As discussed below, we used conservative assumptions for emissions rates, meteorology, and exposure location.

As described in the CalEPA's ''Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants,'' an acute REL value (*http://oehha.ca.gov/media/downloads/crnr/acuterel.pdf*) is defined as ''the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.'' *Id.* at page 2. Acute REL values are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. Acute REL values are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact.

AEGL values were derived in response to recommendations from the National Research Council (NRC). As described in ''Standing Operating Procedures (SOP) of the National Advisory Committee on Acute Exposure Guideline Levels for Hazardous Substances'' (*https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.pdf*),[8] ''the NRC's previous name for acute exposure levels—community emergency exposure levels was replaced by the term AEGL to reflect the broad application of these values to planning, response, and prevention in the community, the workplace, transportation, the military, and the remediation of Superfund sites.'' *Id.* at 2. This document also states that AEGL values ''represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to eight hours.'' *Id.* at 2.

The document lays out the purpose and objectives of AEGL by stating that ''the primary purpose of the AEGL program and the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances is to develop guideline levels for once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.'' *Id.* at 21. In detailing the intended application of AEGL values, the document states that ''[i]t is anticipated that the AEGL values will be used for regulatory and nonregulatory purposes by U.S. Federal and state agencies and possibly the international community in conjunction with chemical emergency response, planning, and prevention programs. More specifically, the AEGL values will be used for conducting various risk assessments to aid in the development of emergency preparedness and prevention plans, as well as real-time emergency response actions, for accidental chemical releases at fixed facilities and from transport carriers.'' *Id.* at 31.

The AEGL–1 value is then specifically defined as ''the airborne concentration (expressed as ppm (parts per million) or mg/m^3 (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.'' *Id.* at 3. The document also notes that, ''Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.'' *Id.* Similarly, the document defines AEGL–2 values as

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[7] The SAB peer review of RTR Risk Assessment Methodologies is available at *http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

[8] National Academy of Sciences (NAS), 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals,* page 2.

''the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.'' *Id.*

ERPG values are derived for use in emergency response, as described in the American Industrial Hygiene Association's ERP Committee document titled, ''ERPGS Procedures and Responsibilities'' (*https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf*), which states that, ''Emergency Response Planning Guidelines were developed for emergency planning and are intended as health based guideline concentrations for single exposures to chemicals.''[9] *Id.* at 1. The ERPG–1 value is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.'' *Id.* at 2. Similarly, the ERPG–2 value is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.'' *Id.* at 1.

As can be seen from the definitions above, the AEGL and ERPG values include the similarly-defined severity levels 1 and 2. For many chemicals, a severity level 1 value AEGL or ERPG has not been developed because the types of effects for these chemicals are not consistent with the AEGL–1/ERPG–1 definitions; in these instances, we compare higher severity level AEGL–2 or ERPG–2 values to our modeled exposure levels to screen for potential acute concerns. When AEGL–1/ERPG–1 values are available, they are used in our acute risk assessments.

Acute REL values for 1-hour exposure durations are typically lower than their corresponding AEGL–1 and ERPG–1 values. Even though their definitions are slightly different, AEGL–1 values are often the same as the corresponding ERPG–1 values, and AEGL–2 values are often equal to ERPG–2 values. Maximum HQ values from our acute screening risk assessments typically result when basing them on the acute REL value for a particular pollutant. In cases where our maximum acute HQ value exceeds 1, we also report the HQ value based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1 value).

To develop screening estimates of acute exposures in the absence of hourly emissions data, generally we first develop estimates of maximum hourly emissions rates by multiplying the average actual annual hourly emissions rates by a default factor to cover routinely variable emissions. We choose the factor to use partially based on process knowledge and engineering judgment. The factor chosen also reflects a Texas study of short-term emissions variability, which showed that most peak emission events in a heavily-industrialized four-county area (Harris, Galveston, Chambers, and Brazoria Counties, Texas) were less than twice the annual average hourly emissions rate. The highest peak emissions event was 74 times the annual average hourly emissions rate, and the 99th percentile ratio of peak hourly emissions rate to the annual average hourly emissions rate was 9.[10] Considering this analysis, to account for more than 99 percent of the peak hourly emissions, we apply a conservative screening multiplication factor of 10 to the average annual hourly emissions rate in our acute exposure screening assessments as our default approach. However, we use a factor other than 10 if we have information that indicates that a different factor is appropriate for a particular source category.

For this source category, we used an acute multiplication factor of 1.2 for all emission sources from nutritional yeast manufacturing facilities. The factor equals the average peak-to-mean ratio developed using 5 years of batch-averaged fermenter VOC concentration data from the facility with the highest emissions in the 2011 NEI. While the current rule requires continuous monitoring of emissions, facilities are required to report whether the percentage of batches that meet emission limits based on the average concentration of VOC emitted from each batch meets the current compliance requirements; not the continuous levels of emissions at the facility. Using the data above, we developed a multiplier to estimate potential acute emissions from each facility in this source category. A further discussion of why this factor was chosen can be found in the memorandum, ''Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Manufacturing of Nutritional Yeast Source Category,'' available in the docket for this rulemaking.

As part of our acute risk assessment process, for cases where acute HQ values from the screening step were less than or equal to 1 (even under the conservative assumptions of the screening analysis), acute impacts were deemed negligible and no further analysis was performed for these HAP. In cases where an acute HQ from the screening step was greater than 1, additional site-specific data were considered to develop a more refined estimate of the potential for acute impacts of concern. For this source category, all acute HQ screening values were less than 1. Therefore, we did not employ additional data refinements.

Ideally, we would prefer to have continuous measurements over time to see how the emissions vary by each hour over an entire year. Having a frequency distribution of hourly emissions rates over a year would allow us to perform a probabilistic analysis to estimate potential threshold exceedances and their frequency of occurrence. Such an evaluation could include a more complete statistical treatment of the key parameters and elements adopted in this screening analysis. Recognizing that this level of data is rarely available, we instead rely on the multiplier approach.

To better characterize the potential health risks associated with estimated acute exposures to HAP, and in response to a key recommendation from the SAB's peer review of the EPA's RTR risk assessment methodologies,[11] we generally examine a wider range of available acute health metrics (*e.g.,* RELs, AEGLs) than we do for our chronic risk assessments. This is in response to the SAB's acknowledgement that there are generally more data gaps and inconsistencies in acute reference values than there are in chronic reference values. In some cases, when

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[9] *ERP Committee Procedures and Responsibilities.* March 2014. American Industrial Hygiene Association.

[10] Allen, et al., *Variable Industrial VOC Emissions and their impact on ozone formation in the Houston Galveston Area.* Texas Environmental Research Consortium, 2004, and available online at: *https://www.researchgate.net/publication/237593060_Variable_Industrial_VOC_Emissions_and_their_Impact_on_Ozone_Formation_in_the_Houston_Galveston_Area*

[11] The SAB peer review of RTR Risk Assessment Methodologies is available at *http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

Reference Value Arrays [12] for HAP have been developed, we consider additional acute values (*i.e.,* occupational and international values) to provide a more complete risk characterization.

4. How did we conduct the multi-pathway exposure and risk screening?

The EPA conducted a screening analysis examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.,* ingestion). We first determined whether any sources in the source category emitted any HAP known to be persistent and bioaccumulative in the environment (PB–HAP). The PB–HAP compounds or compound classes are identified for the screening from the EPA's Air Toxics Risk Assessment Library (available at *http://www2.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library*).

For the Manufacturing of Nutritional Yeast source category, we did not identify emissions of any PB–HAP. Because we did not identify PB–HAP emissions, no further evaluation of multi-pathway risk was conducted for this source category.

5. How did we assess risks considering emissions control options?

The proposed rule amendments include changes to the form of the current emission limits, additional testing requirements, changes to the current monitoring requirements, and updates to the reporting and recordkeeping requirements. The proposed amendments to the emission limits may lead to a slight decrease in the overall emissions from the facilities, but we are unable to quantify this reduction. Facilities will continue to employ current process controls to comply with the emission limits (*i.e.,* they are not required to install additional control technologies); however, the facilities may need to make minor adjustments to the level of process controls to comply with the new limits.

The proposed amendments to testing and monitoring requirements will increase the reliability of the emissions data that is monitored by each facility to ensure that the current emission limits are being met consistently. Therefore, risks considering the proposed amendments are estimated to be the same as actual risks under the current MACT standard.

6. How did we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect

The EPA conducts a screening assessment to examine the potential for adverse environmental effects as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines ''adverse environmental effect'' as ''any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.''

b. Environmental HAP

The EPA focuses on seven HAP, which we refer to as ''environmental HAP,'' in its screening analysis: Five PB–HAP and two acid gases. The five PB–HAP are cadmium, dioxins/furans, polycyclic organic matter (POM), mercury (both inorganic mercury and methyl mercury), and lead compounds. The two acid gases are hydrogen chloride (HCl) and hydrogen fluoride (HF). The rationale for including these seven HAP in the environmental risk screening analysis is presented below.

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The PB–HAP are taken up, through sediment, soil, water, and/or ingestion of other organisms, by plants or animals (*e.g.,* small fish) at the bottom of the food chain. As larger and larger predators consume these organisms, concentrations of the PB–HAP in the animal tissues increases as does the potential for adverse effects. The five PB–HAP we evaluate as part of our screening analysis account for 99.8 percent of all PB–HAP emissions nationally from stationary sources (on a mass basis from the 2005 NEI.

In addition to accounting for almost all of the mass of PB–HAP emitted, we note that the TRIM.FaTE model that we use to evaluate multi-pathway risk allows us to estimate concentrations of cadmium compounds, dioxins/furans, POM, and mercury in soil, sediment and water. For lead compounds, we currently do not have the ability to calculate these concentrations using the TRIM.FaTE model. Therefore, to evaluate the potential for adverse environmental effects from lead compounds, we compare the estimated HEM-modeled exposures from the source category emissions of lead with the level of the secondary National Ambient Air Quality Standards (NAAQS) for lead.[13] We consider values below the level of the secondary lead NAAQS to be unlikely to cause adverse environmental effects.

Due to their well-documented potential to cause direct damage to terrestrial plants, we include two acid gases, HCl, and HF in the environmental screening analysis. According to the 2005 NEI, HCl, and HF account for about 99 percent (on a mass basis) of the total acid gas HAP emitted by stationary sources in the U.S. In addition to the potential to cause direct damage to plants, high concentrations of HF in the air have been linked to fluorosis in livestock. Air concentrations of these HAP are already calculated as part of the human multi-pathway exposure and risk screening analysis using the HEM3–AERMOD air dispersion model, and we are able to use the air dispersion modeling results to estimate the potential for an adverse environmental effect.

The EPA acknowledges that other HAP beyond the seven HAP discussed above may have the potential to cause adverse environmental effects. Therefore, the EPA may include other relevant HAP in its environmental risk screening in the future, as modeling science and resources allow. The EPA invites comment on the extent to which other HAP emitted by the source category may cause adverse environmental effects. Such information should include references to peer-reviewed ecological effects benchmarks that are of sufficient quality for making regulatory decisions, as well as information on the presence of organisms located near facilities within the source category that such benchmarks indicate could be adversely affected.

c. Screening Methodology

For the environmental risk screening analysis, the EPA first determined whether any facilities in the Manufacturing of Nutritional Yeast source category emitted any of the seven environmental HAP. For this source category, we did not identify emissions

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[12] U.S. EPA. Chapter 2.9, *Chemical Specific Reference Values for Formaldehyde in Graphical Arrays of Chemical-Specific Health Effect Reference Values for Inhalation Exposures* (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–09/061, 2009, and available online at *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=211003.*

[13] The secondary lead NAAQS is a reasonable measure of determining whether there is an adverse environmental effect since it was established considering ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

of any of the seven environmental HAP included in the screen. Because we did not identify environmental HAP emissions, we did not conduct a further evaluation of environmental risk.

7. How did we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire ''facility,'' where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. The current NESHAP does not set emission limits for equipment other than fermenters at the affected sources. There is a potential for temporary wastewater storage tanks (*e.g.,* pH adjustment tanks) and dryers to emit small amounts of acetaldehyde at nutritional yeast facilities covered by this subpart. The NEI does not include emissions from wastewater storage tanks at any of the four facilities subject to this rule. Only one of the four facilities has dryers; the NEI did report estimated emissions from these dryers, which were included in the risk assessment for this source category.

We did not perform a separate facility-wide risk assessment for facilities that manufacture nutritional yeast. One facility (American Yeast) reported 43 pounds of additional HAP emissions, composed largely of hexane and formaldehyde, from equipment sources not covered by 40 CFR part 63, subpart CCCC (*e.g.,* boilers, equipment covered by other NESHAP).[14] However, because these emissions were so low and from pollutants with low risk factors, we concluded that a facility-wide risk assessment would yield the same or only very slightly different results as the source category assessment.

8. How did we consider uncertainties in risk assessment?

In the Benzene NESHAP, we concluded that risk estimation uncertainty should be considered in our decision-making under the ample margin of safety framework. Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health protective and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. A more thorough discussion of these uncertainties is included in the ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,'' which is available in the docket for this action.

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.,* not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.,* not including building downwash). Other options that we select have the potential to either under- or overestimate ambient levels (*e.g.,* meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations.

c. Uncertainties in Inhalation Exposure

The EPA did not include the effects of human mobility on exposures in the assessment. Specifically, short-term mobility and long-term mobility between census blocks in the modeling domain were not considered.[15] The approach of not considering short or long-term population mobility does not bias the estimate of the theoretical MIR (by definition), nor does it affect the estimate of cancer incidence because the total population number remains the same. It does, however, affect the shape of the distribution of individual risks across the affected population, shifting it toward higher estimated individual risks at the upper end and reducing the number of people estimated to be at lower risks, thereby increasing the estimated number of people at specific high risk levels (*e.g.,* 1-in-10 thousand or 1-in-1 million).

In addition, the assessment predicted the chronic exposures at the centroid of each populated census block as surrogates for the exposure concentrations for all people living in that block. Using the census block centroid to predict chronic exposures tends to over-predict exposures for people in the census block who live farther from the facility and under-predict exposures for people in the census block who live closer to the facility. Thus, using the census block centroid to predict chronic exposures may lead to a potential understatement or overstatement of the true maximum impact, but is an unbiased estimate of average risk and incidence. We reduce this uncertainty by analyzing large census blocks near facilities using aerial imagery and adjusting the location of the block centroid to better represent the population in the block, as well as adding additional receptor locations where the block population is not well represented by a single location.

The assessment evaluates the cancer inhalation risks associated with pollutant exposures over a 70-year period, which is the assumed lifetime of an individual. In reality, both the length of time that modeled emission sources at facilities actually operate (*i.e.,* more or less than 70 years) and the domestic growth or decline of the modeled industry (*i.e.,* the increase or decrease in the number or size of domestic facilities) will influence the future risks

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[14] Because these emissions originate from sources outside the manufacturing of nutritional yeast source category, they were also excluded from the source category risk analysis.

[15] Short-term mobility is movement from one micro-environment to another over the course of hours or days. Long-term mobility is movement from one residence to another over the course of a lifetime.

posed by a given source or source category. Depending on the characteristics of the industry, these factors will, in most cases, result in an overestimate both in individual risk levels and in the total estimated number of cancer cases. However, in the unlikely scenario where a facility maintains, or even increases, its emissions levels over a period of more than 70 years, residents live beyond 70 years at the same location, and the residents spend most of their days at that location, then the cancer inhalation risks could potentially be underestimated. However, annual cancer incidence estimates from exposures to emissions from these sources would not be affected by the length of time an emissions source operates.

The exposure estimates used in these analyses assume chronic exposures to ambient (outdoor) levels of pollutants. Because most people spend the majority of their time indoors, actual exposures may not be as high, depending on the characteristics of the pollutants modeled. For many of the HAP, indoor levels are roughly equivalent to ambient levels, but for very reactive pollutants or larger particles, indoor levels are typically lower. This factor has the potential to result in an overestimate of 25 to 30 percent of exposures.[16]

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA that should be highlighted. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of humans at the location of the maximum concentration. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and worst-case meteorological conditions co-occur, thus, resulting in maximum ambient concentrations. These two events are unlikely to occur at the same time, making these assumptions conservative. We then include the additional assumption that a person is located at this point during this same time period. For this source category, these assumptions would tend to be worst-case actual exposures as it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and worst-case meteorological conditions occur simultaneously.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and non-cancer effects from both chronic and acute exposures. Some uncertainties may be considered quantitatively, and others generally are expressed in qualitative terms. We note as a preface to this discussion a point on dose-response uncertainty that is brought out in the EPA's *2005 Cancer Guidelines;* namely, that ''the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective'' (EPA's *2005 Cancer Guidelines,* pages 1–7). This is the approach followed here as summarized in the next several paragraphs. A complete detailed discussion of uncertainties and variability in dose-response relationships is given in the ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,'' which is available in the docket for this action.

Cancer URE values used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a ''plausible upper limit to the true value of a quantity'' (although this is usually not a true statistical confidence limit).[17] In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.[18] When developing an upper bound estimate of risk and to provide risk values that do not underestimate risk, health-protective default approaches are generally used. To err on the side of ensuring adequate health protection, the EPA typically uses the upper bound estimates rather than lower bound or central tendency estimates in our risk assessments, an approach that may have limitations for other uses (*e.g.,* priority-setting or expected benefits analysis).

Chronic non-cancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. Specifically, these values provide an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure (RfC) or a daily oral exposure (RfD) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. To derive values that are intended to be ''without appreciable risk,'' the methodology relies upon an uncertainty factor (UF) approach (U.S. EPA, 1993 and 1994), which considers uncertainty, variability, and gaps in the available data. The UF are applied to derive reference values that are intended to protect against appreciable risk of deleterious effects. The UF are commonly default values,[19] *e.g.,* factors of 10 or 3, used in the absence of compound-specific data; where data are available, UF may also be developed using compound-specific information. When data are limited, more assumptions are needed and more UF are used. Thus, there may be a greater tendency to overestimate risk in the sense that further study might support development of reference values that are higher (*i.e.,* less potent) because fewer default assumptions are needed. However, for some pollutants, it is possible that risks may be underestimated.

While collectively termed ''UF,'' these factors account for a number of different quantitative considerations when using observed animal (usually rodent) or human toxicity data in the development of the RfC. The UF are intended to

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[16] U.S. EPA. *National-Scale Air Toxics Assessment for 1996.* (EPA 453/R–01–003; January 2001; page 85.)

[17] IRIS glossary (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary*).

[18] An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

[19] According to the NRC report, ''Science and Judgment in Risk Assessment'' (NRC, 1994) ''[Default] options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk assessment process when the correct scientific model is unknown or uncertain.'' The 1983 NRC report, ''Risk Assessment in the Federal Government: Managing the Process,'' defined default option as ''the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary'' (NRC, 1983a, p. 63). Therefore, default options are not rules that bind the Agency; rather, the Agency may depart from them in evaluating the risks posed by a specific substance when it believes this to be appropriate. In keeping with the EPA's goal of protecting public health and the environment, default assumptions are used to ensure that risk to chemicals is not underestimated (although defaults are not intended to overtly overestimate risk). See EPA, ''An Examination of EPA Risk Assessment Principles and Practices,'' EPA/100/B–04/001, 2004, available at *https://nctc.fws.gov/resources/course-resources/pesticides/Risk%20Assessment/Risk%20Assessment%20Principles%20and%20Practices.pdf.*

account for: (1) Variation in susceptibility among the members of the human population (*i.e.,* inter-individual variability); (2) uncertainty in extrapolating from experimental animal data to humans (*i.e.,* interspecies differences); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (*i.e.,* extrapolating from sub-chronic to chronic exposure); (4) uncertainty in extrapolating the observed data to obtain an estimate of the exposure associated with no adverse effects; and (5) uncertainty when the database is incomplete or there are problems with the applicability of available studies.

Many of the UF used to account for variability and uncertainty in the development of acute reference values are quite similar to those developed for chronic durations, but they more often use individual UF values that may be less than 10. The UF are applied based on chemical-specific or health effect-specific information (*e.g.,* simple irritation effects do not vary appreciably between human individuals, hence a value of 3 is typically used), or based on the purpose for the reference value (*see* the following paragraph). The UF applied in acute reference value derivation include: (1) Heterogeneity among humans; (2) uncertainty in extrapolating from animals to humans; (3) uncertainty in lowest observed adverse effect (exposure) level to no observed adverse effect (exposure) level adjustments; and (4) uncertainty in accounting for an incomplete database on toxic effects of potential concern. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.,* 4 hours) to derive an acute reference value at another exposure duration (*e.g.,* 1 hour).

Not all acute reference values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the reference value or values being exceeded. Where relevant to the estimated exposures, the lack of short-term dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

For a group of compounds that are unspeciated (*e.g.,* glycol ethers), we conservatively use the most protective reference value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.,* ethylene glycol diethyl ether) that does not have a specified reference value, we also apply the most protective reference value from the other compounds in the group to estimate risk.

B. How did we consider the risk results in making decisions for this proposal?

As discussed in section II.A of this preamble, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step process to address residual risk. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR)[20] of approximately [1-in-10 thousand] [*i.e.,* 100-in-1 million].'' 54 FR 38045, September 14, 1989. If risks are unacceptable, the EPA must determine the emissions standards necessary to bring risks to an acceptable level without considering costs. In the second step of the process, the EPA considers whether the emissions standards provide an ample margin of safety ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1-in-1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration, costs, energy, safety, and other relevant factors, an adverse environmental effect.

In past residual risk actions, the EPA considered a number of human health risk metrics associated with emissions from the categories under review, including the MIR, the number of persons in various risk ranges, cancer incidence, the maximum non-cancer HI and the maximum acute non-cancer hazard. *See, e.g.,* 72 FR 25138, May 3, 2007; and 71 FR 42724, July 27, 2006. The EPA considered this health information for both actual and allowable emissions. *See, e.g.,* 75 FR 65068, October 21, 2010; 75 FR 80220, December 21, 2010; 76 FR 29032, May 19, 2011. The EPA also discussed risk estimation uncertainties and considered the uncertainties in the determination of acceptable risk and ample margin of safety in these past actions. The EPA considered this same type of information in support of this action.

The Agency is considering these various measures of health information to inform our determinations of risk acceptability and ample margin of safety under CAA section 112(f). As explained in the Benzene NESHAP, ''the first step judgment on acceptability cannot be reduced to any single factor'' and, thus, ''[t]he Administrator believes that the acceptability of risk under [previous] section 112 is best judged on the basis of a broad set of health risk measures and information.'' 54 FR 38046, September 14, 1989. Similarly, with regard to the ample margin of safety determination, ''the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.'' *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. In responding to comment on our policy under the Benzene NESHAP, the EPA explained that:

> ''[t]he policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing [her] expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in [her] judgment, believes are appropriate to determining what will 'protect the public health'.''

See 54 FR at 38057, September 14, 1989. Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risks. The Benzene NESHAP explained that ''an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk

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[20] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk were an individual exposed to the maximum level of a pollutant for a lifetime.

measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.'' *Id.* at 38045. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: ''EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.'' *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify those HAP risks that may be associated with emissions from other facilities that do not include the source categories in question, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in these categories.

The Agency understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing non-cancer risks, where pollutant-specific exposure health reference levels (*e.g.,* RfCs) are based on the assumption that thresholds exist for adverse health effects. For example, the Agency recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse non-cancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.,* other facilities) to which an individual is exposed may be sufficient to result in increased risk of adverse non-cancer health effects. In May 2010, the SAB advised the EPA ''that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area.'' [21]

In response to the SAB recommendations, the EPA is incorporating cumulative risk analyses into its RTR risk assessments, including those reflected in this proposal. The Agency is: (1) Conducting facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) considering sources in the same category whose emissions result in exposures to the same individuals; and (3) for some persistent and bioaccumlative pollutants, analyzing the ingestion route of exposure. In addition, the RTR risk assessments have always considered aggregate cancer risk from all carcinogens and aggregate non-cancer HI from all non-carcinogens affecting the same target organ system.

Although we are interested in placing source category and facility-wide HAP risks in the context of *total* HAP risks from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Because of the contribution to total HAP risk from emission sources other than those that we have studied in depth during this RTR review, such estimates of total HAP risks would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

C. How did we perform the technology review?

Our technology review focused on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identified such developments, in order to inform our decision of whether it is ''necessary'' to revise the emissions standards, we analyzed the technical feasibility of applying these developments and the estimated costs, energy implications, non-air environmental impacts, as well as considering the emission reductions. We also considered the appropriateness of applying controls to new sources versus retrofitting existing sources.

Based on our analyses of the available data and information, we identified potential developments in practices, processes, and control technologies. For this exercise, we considered any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed (or last updated) the NESHAP, we reviewed a variety of data sources in our investigation of potential practices, processes, or controls to consider. Among the sources we reviewed were the NESHAP for various industries that were promulgated since the MACT standards being reviewed in this action. We reviewed the regulatory requirements and/or technical analyses associated with these regulatory actions to identify any practices, processes, and control technologies considered in these efforts that could be applied to emission sources in the Manufacturing of Nutritional Yeast source category, as well as the costs, non-air impacts, and energy implications associated with the use of these technologies. Additionally, we requested information from facilities regarding developments in practices, processes, or control technology. Finally, we reviewed information from other sources, such as state and/or local permitting agency databases and industry-supported databases.

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[21] The EPA's responses to this and all other key recommendations of the SAB's advisory on RTR risk assessment methodologies (which is available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA–SAB–10–007-unsigned.pdf*) are outlined in a memorandum to this rulemaking docket from David Guinnup titled, ''EPA's Actions in Response to the Key Recommendations of the SAB Review of RTR Risk Assessment Methodologies.''

IV. Analytical Results and Proposed Decisions

A. What are the results of the risk assessment and analyses?

As described above, for the Manufacturing of Nutritional Yeast source category, we conducted an inhalation risk assessment for all HAP emitted. We present results of the risk assessment briefly below and in more detail in the document: ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,'' which is available in the docket for this action.

1. Inhalation Risk Assessment Results

Table 2 of this preamble provides a summary of the results of the inhalation risk assessment for the source category. As discussed in section III.A.2 of this preamble, we set MACT-allowable HAP emission levels at nutritional yeast manufacturing facilities equal to actual emissions. For more detail about the MACT-allowable emission levels, see the memorandum, ''Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

TABLE 2—NUTRITIONAL YEAST MANUFACTURING INHALATION RISK ASSESSMENT RESULTS

Number of facilities [1]	Maximum individual cancer risk (in 1 million) [2]		Estimated population at increased risk of cancer ≥ 1-in-1 Million		Estimated annual cancer incidence (cases per year)		Maximum chronic non-cancer TOSHI [3]		Maximum screening acute non-cancer HQ [4]	
	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level	Based on actual emissions level [2]	Based on allowable emissions level
4	2	2	750	750	0.0009	0.0009	0.08	0.08	HQ_{REL} = 0.2	HQ_{REL} = 0.2.

[1] Number of facilities evaluated in the risk analysis.

[2] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category.

[3] Maximum TOSHI. The target organ with the highest TOSHI for the Manufacturing of Nutritional Yeast source category is the respiratory system.

[4] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. HQ values shown use the lowest available acute threshold value, which in most cases is the REL. When HQ values exceed 1, we also show HQ values using the next lowest available acute dose-response value. See section III.A.3 of this preamble for explanation of acute dose-response values.

The results of the inhalation risk modeling using actual emissions data, as shown in Table 2 of this preamble, indicate that the maximum lifetime individual cancer risk could be up to 2-in-1 million, the maximum chronic non-cancer TOSHI value could be up to 0.08, and the maximum off-facility site acute HQ value could be up to 0.2. The total estimated national cancer incidence from these facilities based on actual emission levels is 0.0009 excess cancer cases per year or 1 case in every 1,100 years.

2. Acute Risk Results

Table 2 of this preamble shows the acute risk results for the Manufacturing of Nutritional Yeast source category. The screening analysis for acute impacts was based on an industry specific multiplier of 1.2, to estimate the peak emission rates from the average rates. For more detailed acute risk results, refer to the draft document: ''Residual Risk Assessment for the Manufacturing of Nutritional Yeast Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,'' which is available in the docket for this action.

3. Multi-Pathway Risk Screening Results

There are no PB–HAP emitted by facilities in this source category. Therefore, we do not expect any human health multi-pathway risks as a result of emissions from this source category.

4. Environmental Risk Screening Results

The emissions data for the Manufacturing of Nutritional Yeast source category indicate that sources within this source category do not emit any of the seven pollutants that we identified as ''environmental HAP,'' as discussed earlier in this preamble. Additionally, the processes and materials used in the source category typically do not emit any of the seven environmental HAP. Also, we are unaware of any adverse environmental effect caused by emissions of HAP that are emitted by this source category (acetaldehyde). Therefore, we do not expect an adverse environmental effect as a result of HAP emissions from this source category.

5. Facility-Wide Risk Results

As explained in section III.A.7 of this preamble, we did not perform a separate facility-wide risk assessment because we expect facility-wide risks to be equal to the risks we assessed for this source category.

6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups within the population near the four nutritional yeast manufacturing facilities that are subject to the NESHAP. In this analysis, we evaluated the distribution of HAP-related cancer risks and non-cancer hazards from the nutritional yeast manufacturing facilities across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks. The methodology and the results of the demographic analyses are included in a technical report, ''Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Nutritional Yeast Manufacturing Facilities,'' available in the docket for this action.

The analysis indicates that the minority population living within 50 km (1,700,000 people, of whom 41 percent are minority) and within 5 km (131,567 people, of whom 68 percent are minority) of the four nutritional yeast manufacturing facilities is greater than the minority population found nationwide (28 percent). The specific demographics of the population within 5 and 50 km of the facilities indicate potential disparities in risks in certain demographic groups, including the ''African American,'' ''Below the Poverty Level,'' and ''Over 25 and without high school diploma'' groups.

When examining the risk levels of those exposed to emissions from the four nutritional yeast manufacturing facilities, we find approximately 750 persons are exposed to a cancer risk greater than or equal to 1-in-1 million, and the highest cancer risk for these individuals is less than 2-in-1 million. Of these 750 persons, 100 percent of them are defined as minority. When examining the noncancer risks surrounding these facilities, no one is predicted to have a chronic non-cancer TOSHI greater than 1.

B. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effects?

1. Risk Acceptability

As noted in section III.B of this preamble, we weigh all health risk factors in our risk acceptability determination, including the cancer MIR, the number of persons in various cancer and non-cancer risk ranges, cancer incidence, the maximum non-cancer TOSHI, the maximum acute non-cancer HQ, the extent of non-cancer risks, the potential for adverse environmental effects, the distribution of cancer and non-cancer risks in the exposed population, and risk estimation uncertainties (54 FR 38044, September 14, 1989).

For the Manufacturing of Nutritional Yeast source category, the risk analysis indicates that the cancer risks to the individual most exposed could be up to 2-in-1 million due to actual emissions and up to 2-in-1 million based on allowable emissions. As explained in section III.A.2 of this preamble, we determined that actual emissions provide an accurate representation of maximum emissions from the source category and used the actual emissions in both steps of the risk assessment (*i.e.,* determination of risk based on actual and MACT-allowable emissions). These risks are considerably less than 100-in-1 million, which is the presumptive upper limit of acceptable risk. The risk analysis also shows very low cancer incidence (0.0009 cases per year), as well as no potential for adverse chronic or multi-pathway health effects. In addition, the risk assessment indicates no significant potential for multi-pathway health effects or adverse environmental effects. The acute non-cancer risks based on actual and allowable emissions are all below an HQ of 1. Therefore, we find there is little potential concern of acute non-cancer health impacts from actual and allowable emissions.

Considering all of the health risk information and factors discussed above, including the uncertainties discussed in section III.A.8 of this preamble, we propose to find that the risks from the Manufacturing of Nutritional Yeast source category are acceptable.

2. Ample Margin of Safety Analysis

Although we are proposing that the risks from the Manufacturing of Nutritional Yeast source category are acceptable, risk estimates for approximately 750 individuals in the exposed population are above 1-in-1 million at the actual and MACT-allowable emissions levels. Consequently, we further considered whether the MACT standards for the Manufacturing of Nutritional Yeast source category provide an ample margin of safety to protect public health. In this ample margin of safety analysis, we investigated available emissions control options that might reduce the risk from the source category. We considered this information along with all of the health risks and other health information considered in our determination of risk acceptability.

As discussed in section IV.C of this preamble, during the technology review for this source category, we evaluated two control technologies for reducing acetaldehyde emissions from fermenters at nutritional yeast facilities: Thermal oxidizers and wet (packed bed) scrubbers. Thermal oxidizers have the potential to reduce total acetaldehyde emissions from this source category by 11 tpy to 36 tpy, for a total of 90 tpy for the industry, but would also lead to increases in energy use and emissions of approximately 89 tpy of nitrogen oxides (NO_X) from these facilities. The cost effectiveness for thermal oxidizers varied per facility, with an average cost of $56,000 per ton of acetaldehyde reduced. The average cost effectiveness for packed bed scrubbers was $74,000 per ton of acetaldehyde per facility. The use of packed bed scrubbers would also lead to additional environmental impacts, such as increased energy and water usage, as well as the need to use and dispose of solvents. These cost-effectiveness values are significantly higher than values that we have historically deemed to be cost effective for organic HAP in other NESHAP. Due to the additional environmental impacts that would be imposed and the low level of current risk, along with the substantial costs associated with these options, we are proposing that additional emissions controls for this source category are not necessary to provide an ample margin of safety.

3. Environmental Effects

We did not identify emissions of any of the seven environmental HAP included in our environmental risk screening, and are unaware of any adverse environmental effects caused by HAP emitted by this source category (acetaldehyde). Therefore, we do not expect there to be an adverse environmental effect as a result of HAP emissions from this source category and we are proposing that it is not necessary to set a more stringent standard to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

C. What are the results and proposed decisions based on our technology review?

In order to fulfill our obligations under CAA section 112(d)(6), we conducted a technology review to identify developments in practices, processes, and control technologies that may advise revisions to the current NESHAP standards applicable to the Manufacturing of Nutritional Yeast source category (*i.e.,* 40 CFR part 63, subpart CCCC). In conducting our technology review, we utilized the RBLC database, reviewed title V permits for each nutritional yeast facility, and reviewed regulatory actions related to emissions controls at similar sources that could be applicable to nutritional yeast manufacturing facilities.

After reviewing information from the sources above, we identified two control technologies for further evaluation that are technically feasible for use at nutritional yeast facilities: thermal oxidizers and wet scrubbers.[22] These control technologies were identified both in the RBLC database and in a review of the miscellaneous organic chemical manufacturing NESHAP (MON). The RBLC database contains multiple sources with similar production processes as nutritional yeast manufacturing facilities that employ thermal oxidizers or wet scrubbers, *e.g.,* fermenters at ethanol facilities. We also identified the MON in particular as being a potentially useful analog for manufacturing of nutritional yeast because the MON regulates

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[22] Additional information about this determination is documented in the memorandum, ''Technology Review for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

emissions from ethanol fermenters (the same sources identified in the RBLC) that are located at facilities that are major sources of HAP emissions. Our review of this rule revealed that facilities use thermal oxidizers as a control technology to comply with the process vent emission limits in the MON.

After identifying control technologies that are technically feasible for reducing acetaldehyde emissions from nutritional yeast fermenters, we then evaluated the costs and emissions reductions associated with installing regenerative thermal oxidizers (RTOs) and packed bed scrubbers at each of the four nutritional yeast facilities. The total capital investment to install RTOs ranged from $2 million to $6.9 million per facility for a total of approximately $14.9 million for the industry. Annual costs for each facility were approximately $0.8 million to $2.2 million, for a total of $5.2 million per year for the industry. Applying a control efficiency of 98 percent, acetaldehyde emissions for each facility would be reduced by approximately 11 tpy to 36 tpy, for a total of 90 tpy for the industry. To install RTOs at each facility, the resulting cost effectiveness ranged from $32,000 to $90,000 per ton of acetaldehyde reduced. Furthermore, use of RTOs would result in increased energy use and NO_X emissions of approximately 89 tpy from nutritional yeast manufacturing facilities. Additional information about the assumptions and methodologies used in these calculations is documented in the memorandum, ''Technology Review for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

The total capital investment to install packed bed scrubbers on fermenters ranged from $3 million to $11.6 million per facility for a total of about $24.5 million for the industry. Annual costs for each facility were approximately $0.8 million to $2.5 million, for a total of $5.8 million per year for the industry. Applying a control efficiency of 85 percent, acetaldehyde emissions for each facility would be reduced by approximately 9.4 tpy to 31 tpy, for a total of 78 tpy for the industry. To install packed bed scrubbers at each facility, the resulting cost effectiveness ranged from $43,000 to $110,000 per ton of acetaldehyde reduced. Furthermore, the use of packed bed scrubbers would lead to increased energy usage and other environmental impacts, such as the usage and disposal of water and caustic solutions (*e.g.,* sodium hydroxide). These cost-effectiveness values are significantly higher than values that we have historically deemed to be cost effective for organic HAP in other NESHAP. Additional information about the assumptions and methodologies used in these calculation is documented in the memorandum, ''Technology Review for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

Considering the high costs per ton of acetaldehyde reduced and potential adverse environmental impacts associated with the installation of RTOs or packed bed scrubbers, we did not consider these technologies to be cost effective for further reducing acetaldehyde emissions from fermenters at nutritional yeast manufacturing facilities. In light of the results of the technology review, we conclude that changes to the fermenter emission limits are not warranted pursuant to CAA section 112(d)(6). We solicit comment on our proposed decision.

D. What other actions are we proposing?

We are proposing revisions to the malfunction provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of startup, shutdown, and malfunction (SSM). We are proposing revisions to the form of the VOC emission limits for fermenters to address this issue. We also are proposing various other changes to testing, monitoring, recordkeeping, and reporting requirements. Our analyses and proposed changes related to these issues are presented below.

1. Fermenter VOC Emission Limits

The Manufacturing of Nutritional Yeast NESHAP currently requires that 98 percent of all batches meet the fermenter batch average VOC emission limits, on a 12-month rolling basis. However, this requirement allows 2 percent of the batches to exceed the standard. This formulation of the standard is in direct conflict with the statutory requirement that emission standards apply at all times, as discussed in *Sierra Club* v. *EPA.* 551 F. 3d 1019 (D.C. Cir. 2008). As a result, the EPA reviewed the current fermenter VOC emission limits and is proposing revisions to the form of the standard. We are proposing to revise the form of the standard in Table 1 to 40 CFR part 63, subpart CCCC such that each batch must meet the existing VOC concentration limits (300 ppmv for stock fermentation, 200 ppmv for first generation fermentation, and 100 ppmv for trade fermentation), which is referred to as the ''Batch Option'' in the proposed revisions.

In recognition that the yeast manufacturing process is biological and does not produce the exact same level of emissions from every batch, the proposed amendments also include an alternative compliance method in Table 1 to 40 CFR part 63, subpart CCCC that allows facilities to average the VOC concentration data from all batches within each fermentation stage over a rolling 12-month period. When manufacturing yeast, increased acetaldehyde levels indicate inefficiencies in the manufacturing process; consequently, facilities have a financial incentive to reduce emissions as much as possible through process controls. However, to ensure that the averaging method will be at least as stringent as the emission standards without averaging, we are proposing a 5-percent discount factor in the VOC emission limit for each stage, *i.e.,* 285 ppmv for stock fermentation, 190 ppmv for first generation fermentation, and 95 ppmv for trade fermentation. For example, if this alternative option is selected, all batch average VOC concentration data for the trade fermentation stage in a 12-month period must be averaged together and this average must not exceed 95 ppmv VOC instead of the limit of 100 ppmv VOC for individual batches. This option is referred to as the ''Average Option'' in the proposed revisions to 40 CFR part 63, subpart CCCC. This alternative provides sources with flexibility on ways to comply with the standard, while maintaining the sources' accountability for meeting health and environmental goals and maintaining the enforceability of the emission limits by regulatory authorities. We expect that allowing facilities to average emissions over the period of 1 year will provide flexibility for changes in production over time without allowing for wide-ranging fluctuations in HAP emissions. The use of a rolling annual calculation period with semiannual compliance reports, including monthly updates of the annual average emission calculations, protects against emission peaks so health and welfare effects are avoided. This proposed alternative method of demonstrating compliance also minimizes the recordkeeping and reporting impacts of the changes for facilities and regulatory authorities, since the current rule requires the same compliance periods. The EPA requests comment on the proposed revisions to the form of the fermenter VOC emission limits. Additionally, we request comment on whether it is appropriate to use a discount factor and what value between 0 and 10 percent should be selected for the discount factor.

We are also proposing changes to 40 CFR 63.2171 and Table 4 to 40 CFR part 63, subpart CCCC that specify the procedures facilities must use to demonstrate continuous compliance with either of the two proposed forms of the emission limits in Table 1 to 40 CFR part 63, subpart CCCC. The proposed changes require facilities to immediately begin demonstrating continuous compliance with one of the two proposed forms of the emission limits (*i.e.,* the Average Option or the Batch Option) upon the effective date of the final rule.

For the proposed Average Option, the changes to 40 CFR 63.2171 and Table 4 to 40 CFR part 63, subpart CCCC require facilities to calculate compliance on a monthly basis using data from every batch produced during the previous 12 months. The proposed amendments to 40 CFR 63.2150 remove the exemption that allows facilities to exceed emissions during periods of malfunction. The proposed amendments to 40 CFR 63.2170 retain the provision that data recorded during monitoring malfunctions, associated repairs, and required quality assurance or quality control activities must not be used to report emissions. Therefore, data from batches that were produced during periods of malfunctions over the past 12 months, other than those related to the monitoring system, must now be included in the calculations used to determine compliance. Additionally, instead of calculating a single determination of compliance based on the emissions from all batches regardless of fermentation stage, facilities must now determine compliance for batches within each of the three fermentation stages that have specific emission limits in Table 1 to 40 CFR part 63, subpart CCCC. Based on information collected during the site visits, the EPA expects that facilities have the necessary data available to make these changes to the methods used to determine compliance upon promulgation of the final rule.

For the proposed Batch Option, the changes to 40 CFR 63.2171 and Table 4 to 40 CFR part 63, subpart CCCC require facilities to demonstrate that the average VOC concentration for each individual batch produced during a semiannual compliance period did not exceed the applicable emission limits. As noted above, this now includes data from batches that were produced during periods of malfunctions, other than malfunctions related to the monitoring system. Based on information collected during the site visits, the EPA expects that facilities have the necessary data available to make these changes to the methods used to determine compliance upon promulgation of the final rule.

The EPA requests comment on the proposed timeframe to demonstrate compliance using the revised form of the emission limits upon promulgation of the final rule and the availability of data necessary to comply within this timeframe.

2. Testing, Monitoring, Recordkeeping, and Reporting Requirements

We propose to revise the rule's testing, monitoring, recordkeeping, and reporting requirements in five ways: (1) Owners or operators must demonstrate compliance by using a VOC continuous emission monitoring system (CEMS) to determine the VOC concentration in the fermenter exhaust (*i.e.,* we are removing the option to monitor brew ethanol and calculate VOC concentration using a correlation); (2) owners or operators may not use a gas chromatographic (GC) CEMS to monitor VOC concentration; (3) owners or operators must have valid CEMS data from each hour of the entire batch monitoring period and report periods of missing data as deviations; (4) owners or operators of VOC CEMS must conduct annual performance tests (relative accuracy test audits (RATAs)) using Procedure 1 of appendix F to part 60 to evaluate the performance of the installed VOC CEMS over an extended period of time; and (5) owners or operators must provide compliance reports electronically.

a. Proposed Removal of the Option to Monitor Brew Ethanol

Subpart CCCC of 40 CFR part 63 currently allows owners or operators to monitor brew ethanol in the fermenter liquid and determine an annual correlation to VOC concentration in the fermenter exhaust in order to demonstrate compliance with fermenter VOC emission limits. We are proposing to revise the requirements of 40 CFR 63.2166 and 63.2171 and Table 3 and Table 4 to 40 CFR part 63, subpart CCCC to remove the option to monitor brew ethanol.

Currently, one facility demonstrates compliance by monitoring brew ethanol and submits annual reports showing the results of performance testing and development of the correlation equation for each fermentation stage.[23] We reviewed reports for the past 5 years (2012–2016) and found that individual equations showed strong correlations with the data obtained during the applicable performance tests. However, the reports also showed a high level of variability between the equations for each fermentation stage across the 5-year period. A fermentation stage characterized by a correlation equation with a higher slope results in higher VOC emissions estimates per percent ethanol measured in the brew, while a correlation equation with a lower slope results in lower VOC emissions estimates per percent ethanol in the brew. Therefore, applying equations with different slopes to the same brew ethanol concentration yields different estimates of VOC emissions. A review of reports from the previous 5 years shows a high level of inconsistency in the amount of VOC emissions estimated for a particular brew ethanol percentage each year. The practical effect of these variations is that estimates of VOC concentrations from a given fermentation stage can almost double for a single brew ethanol concentration, depending on the correlation equation used. This has the greatest effect on concentrations at the higher end of the normal range for each stage of fermentation. To illustrate the effect, we selected a brew ethanol concentration at the higher end of the range of brew ethanol concentration data for each of the fermentation stages and determined the corresponding range of VOC concentrations, based on the most recent 5 years of correlation data. The results showed that for each fermentation stage, a given brew ethanol concentration would meet the compliance emission limit in some years, but greatly exceed it in other years; see Table 3 of this preamble. The 5 years of correlation data are presented in the memorandum, ‘‘Brew Ethanol Correlation Review for the Manufacturing of Nutritional Yeast Source Category,’’ which is available in the docket for this action.

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[23] The correlation equation is used to estimate the concentration of VOC in the fermenter exhaust for a given percentage of ethanol (measured in the fermenter brew).

TABLE 3—RANGE OF VOC CONCENTRATION FOR EACH FERMENTATION STAGE, BASED ON BREW ETHANOL CORRELATION DATA

Fermentation stage	Brew ethanol concentration, %	VOC concentration range, ppmv as propane	VOC emission limitation, ppmv as propane[1]
Third-to-last	0.25	188 to 372	300
Second-to-last	0.20	109 to 227	200
Last	0.125	73 to 170	100

[1] As specified in Table 1 to 40 CFR part 63, subpart CCCC.

As mentioned above, individual equations typically exhibited strong statistical correlations for the data used to develop them, which indicates that there is a relationship between VOC emissions and brew ethanol concentration for a given batch. However, the observed variability between equations indicates the correlation between VOC emissions and brew ethanol concentration is different for each batch. This means that the correlation developed for one batch may not be representative of the correlation between VOC emissions and brew ethanol concentration for any other batch. Given that estimates of VOC concentrations from a given fermentation stage can almost double for a single brew ethanol concentration, depending on the correlation equation used, a batch that appears to be in compliance could, in fact, be out of compliance.

The manufacturing of yeast is a biological process and some degree of variation is expected. However, emissions are also determined by a few key process parameters, including the amount of available oxygen and the composition and amount of the sugar and nutrient mixture fed to the yeast in each batch. As noted on the site visits, the amount of oxygen does not vary significantly between batches. Fermenters are equipped with aeration systems, which operate at full capacity for every batch. In contrast, the composition of the sugar source can vary greatly from one batch to the next. Market factors (*e.g.,* price, availability, competition) drive the purchase of sugar sources, such as molasses, throughout the year. Purchases are made frequently and there is some on-site storage, allowing operators of nutritional yeast manufacturing facilities to blend different materials together at times. While the composition of the mixture is optimized for yeast growth given the materials on hand at any given time, the specific composition fluctuates throughout the year. It is likely that the differences in composition of the sugar source for each batch explains much of the variance observed in the correlation equations analyzed above.

In order to establish a reliable correlation between VOC emissions and brew ethanol for each batch, a new performance test would need to be conducted every time the sugar source changes. At facilities where the sugar source changes frequently, this requirement would pose a significant financial and logistic burden with results that were of limited applicability. In addition, it would create significant challenges for the regulatory authority responsible for enforcing the frequency and validity of the performance tests.

Reliable emissions data are critical to ensuring compliance with the established emission limits, which is necessary to reduce the emissions of HAP and protect public health and the environment. Therefore, the EPA is proposing to remove the option to demonstrate compliance with the emission limits by monitoring brew ethanol, and to require all facilities to monitor fermenter exhaust using CEMS.

We are proposing to allow facilities to continue to monitor brew ethanol for up to 1 year after the promulgation of any such proposed rule revisions. This transition period would help ensure continuous compliance with the emission limits while allowing time to install CEMS (see proposed 40 CFR 63.2171). Additionally, because no new facilities are currently under construction, we are proposing to remove requirements in 40 CFR 63.2160, 63.2166, 63.2180, and Table 3 to 40 CFR part 63, subpart CCCC related to the demonstration of initial compliance by monitoring brew ethanol. New affected sources would not be able to demonstrate initial compliance by monitoring brew ethanol.

We are proposing to revise language in 40 CFR 63.2164 to reference a ''brew ethanol monitor'' and not a ''CEMS'' to monitor brew ethanol. CEMS is not the correct term to describe the monitoring device for brew ethanol. The term ''brew ethanol monitor'' is already defined in the current rule, and the proposed revisions correctly incorporate its use into the rule language.

The EPA specifically requests comments on whether the option to demonstrate compliance by monitoring brew ethanol and developing a correlation to VOC concentration in the fermenter exhaust should be retained if performance tests to determine the correlation are conducted more frequently. Commenters should address the frequency of the correlation recalculation (using performance testing) needed to provide reliable emissions data that will consistently reflect accurate emissions for each batch and explain the basis for their conclusions.

b. Proposed Removal of GC CEMS

The current rule allows the use of CEMS that generate a single combined response value for VOC (VOC CEMS) or that rely upon GC CEMS, if they are constructed and operated according to the applicable Performance Specification (PS) of 40 CFR part 60, appendix B, to monitor VOC emissions (40 CFR 63.2163). However, nutritional yeast manufacturing facilities emit a mixture of VOCs and the emission limits for these facilities are stated for total VOC (as opposed to specific VOC species). While VOC CEMS constructed and operated according to PS 8 can measure total VOCs, GC CEMS constructed and operated according to PS 9 are suitable for measuring a few specific VOC species. Based on information collected during the site visits, we are not aware of any facilities currently using GC CEMS. Therefore, we propose to revise 40 CFR 63.2163 to remove the option to use GC CEMS to monitor VOC concentration. The EPA requests comment on this proposed revision.

c. Proposed Collection of All Valid CEMS Data From the Entire Batch Monitoring Period.

The current rule requires owners or operators who monitor fermenter exhaust to have valid CEMS data from at least 75 percent of the full hours over the entire batch, and that a valid hour of data must have one data point for each 30-minute period. In the 15 years since the rule was promulgated, there have been continued improvements in CEMS reliability as well as a change in the data collection approach. In many NESHAP, CEMS are required to collect, process, and report results of the sampling at least once every 15 minutes. Some CEMS are able to complete the process cycle more often than every 15 minutes. Moreover, many regulatory authorities no longer have minimum valid data requirements for emissions data. Rather, each source owner or operator is expected to collect as much data as possible and to report periods of missing data, along with the reason for such periods, to the regulatory authority who determines what, if any, follow-up action would be required.[24] Such an approach is included in our recently promulgated Mercury Air Toxics Standard (MATS). MATS requires owners or operators to collect data at all times the electric generation unit (EGU) operates; failure to collect the required data is a deviation from monitoring requirements. EGU owners or operators are to describe, explain, and report deviations in ongoing compliance reports and to keep records of deviations.[25]

We propose to revise 40 CFR 63.2163, 63.2170, 63.2181(c)(7), and 63.2182(b)(9) to require owners or operators of nutritional yeast sources to follow this model. Owners or operators would be required to collect VOC concentration data at all times of batch operation. Failure to collect VOC concentration data would be a deviation of monitoring requirements and would trigger generation of a report identifying the periods during which data were not collected, a description of the deviation event, and an explanation as to why the deviation occurred. The owner or operator would also be required to maintain records of each deviation. In addition, owners or operators would report the hours of deviation, along with the hours of batch operation. Relying on reported information, regulatory authorities would determine what, if any, follow-up correction or enforcement action should occur. The EPA requests comment on this proposed revision and its incorporation into the rule.

d. Proposed Use of Procedure 1 of Appendix F to Part 60 for VOC CEMS

The current rule requires owners or operators of nutritional yeast manufacturing facilities to monitor compliance using either VOC or GC CEMS. Additionally, the rule exempts owners or operators that use a VOC CEMS with a flame ionization analyzer from conducting the RATAs required by PS 8. As discussed in section IV.D.2.b of this preamble, we are proposing to remove the option to monitor compliance using a GC CEMS and the related installation requirements. The current rule requires owners or operators to install and certify VOC CEMS according to PS 8. Use of PS 8 ensures that the VOC CEMS has been installed properly, but it lacks ongoing quality assurance and quality control (QA/QC) procedures to ensure that a properly installed VOC CEMS continues to operate appropriately. Such procedures are included in Procedure 1 of appendix F to part 60. In order to clarify the minimum requirements for owners or operators to ensure their VOC CEMS continue to produce valid data, we propose to revise 40 CFR 63.2163 to include the requirements of Procedure 1 of appendix F to part 60, where propane would be used for the calibration gas and Method 25A would be used as the Reference Method (RM). In doing so, we are also removing the exemption for owners and operators of nutritional yeast manufacturing facilities that monitor VOC emissions using a flame ionization analyzer from conducting the relative-accuracy test PS 8 requires. Incorporation of a consistent set of ongoing QA/QC requirements will not only provide assurance that the ongoing collected data are valid, but also ensure a consistent basis for collecting those data.

Moreover, we propose to replace the outdated reference 2 of PS 8, ''A Procedure for Establishing Traceability of Gas Mixtures to Certain National Bureau of Standards Standard Reference Materials,'' with the current version of our traceability protocol. In the revised regulatory text of 40 CFR part 63, subpart CCCC, the EPA is proposing to incorporate by reference EPA/600/R–12/531, EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, May 2012, at 40 CFR 63.2163(b)(2), in accordance with requirements of 1 CFR 51.5. The protocol is used to certify calibration gases for continuous emission monitors and specifies methods for assaying gases and establishing traceability to National Institute of Standards and Technology reference standards.[26] The EPA has made, and will continue to make, documents that are incorporated by reference generally available electronically through *http://www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information). The EPA requests comment on the proposed QA/QC procedures and CEMS RATA revisions.

e. Electronic Reporting

Through this action, the EPA is proposing to amend 40 CFR 63.2181(a) to require that owners or operators of nutritional yeast manufacturing facilities submit electronic copies of compliance reports, which include performance test and performance evaluation results, through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). The EPA believes that the electronic submittal of the reports addressed in this proposed rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community. Under current requirements, paper reports are often stored in filing cabinets or boxes, which make the reports more difficult to obtain and use for data analysis and sharing. Electronic storage of such reports would make data more accessible for review, analyses, and sharing. Electronic reporting can also eliminate paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

In 2011, in response to Executive Order 13563, the EPA developed a plan[27] to periodically review its regulations to determine if they should be modified, streamlined, expanded, or repealed in an effort to make regulations more effective and less burdensome. The plan includes replacing outdated paper reporting with electronic reporting. In keeping with this plan and the White House's Digital Government

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[24] See Indiana's *Compliance Branch CEMS Guidance Manual,* section 4.5 on page 19 of chapter 2, available at *http://www.in.gov/idem/files/aircom_cems_chapter_2.pdf.*

[25] See 40 CFR 63.10020(b), 10020(d), 10021(g), 10031(c)(9), and 10032(a)(4).

[26] Additional information about the traceability protocol is available at *https://www.epa.gov/air-research/epa-traceability-protocol-assay-and-certification-gaseous-calibration-standards.*

[27] EPA's Final Plan for Periodic Retrospective Reviews, August 2011. Available at: *https://www.epa.gov/sites/production/files/2015–09/documents/eparetroreviewplan-aug2011_0.pdf.*

Strategy,[28] in 2013 the EPA issued an agency-wide policy specifying that new regulations will require reports to be electronic to the maximum extent possible. By requiring electronic submission of specified reports in this proposed rule, the EPA is taking steps to implement this policy.

The EPA Web site that stores the submitted electronic data, WebFIRE, will be easily accessible to everyone and will provide a user-friendly interface that any stakeholder could access. By making data readily available, electronic reporting increases the amount of data that can be used for many purposes. One example is the development of emissions factors. An emissions factor is a representative value that attempts to relate the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant (*e.g.,* kilograms of particulate emitted per megagram of coal burned). Such factors facilitate the estimation of emissions from various sources of air pollution and are an important tool in developing emissions inventories, which in turn are the basis for numerous efforts, including trends analysis, regional and local scale air quality modeling, regulatory impact assessments, and human exposure modeling. Emissions factors are also widely used in regulatory applicability determinations and in permitting decisions.

The EPA has received feedback from stakeholders asserting that many of the EPA's emissions factors are outdated or not representative of a particular industry emission source. While the EPA believes that the emissions factors are suitable for their intended purpose, we recognize that the quality of emissions factors varies based on the extent and quality of underlying data. We also recognize that emissions profiles on different pieces of equipment can change over time due to a number of factors (fuel changes, equipment improvements, industry work practices), and it is important for emissions factors to be updated to keep up with these changes. The EPA is currently pursuing emissions factor development improvements that include procedures to incorporate the source test data that we are proposing be submitted electronically. By requiring the electronic submission of the reports identified in this proposed action, the EPA would be able to access and use the submitted data to update emissions factors more quickly and efficiently, creating factors that are characteristic of what is currently representative of the relevant industry sector. Likewise, an increase in the number of test reports used to develop the emissions factors will provide more confidence that the factor is of higher quality and representative of the whole industry sector.

Additionally, by making the records, data, and reports addressed in this proposed rulemaking readily available, the EPA, the regulated community, and the public will benefit when the EPA conducts its CAA-required technology and risk-based reviews. As a result of having performance test reports and air emission reports readily accessible, our ability to carry out comprehensive reviews will be increased and achieved within a shorter period of time. These data will provide useful information on control efficiencies being achieved and maintained in practice within a source category and across source categories for regulated sources and pollutants. These reports can also be used to inform the technology-review process by providing information on improvements to add-on control technology and new control technology.

Under an electronic reporting system, the EPA's Office of Air Quality Planning and Standards (OAQPS) would have air emissions and performance test data in hand; OAQPS would not have to collect these data from the EPA Regional offices or from delegated air agencies or industry sources in cases where these reports are not submitted to the EPA Regional offices. Thus, we anticipate fewer or less substantial information collection requests (ICRs) in conjunction with prospective CAA-required technology and risk-based reviews may be needed. We expect this to result in a decrease in time spent by industry to respond to data collection requests. We also expect the ICRs to contain less extensive stack testing provisions, as we will already have stack test data electronically. Reduced testing requirements would be a cost savings to industry. The EPA should also be able to conduct these required reviews more quickly, as OAQPS will not have to include the ICR collection time in the process or spend time collecting reports from the EPA Regional Offices. While the regulated community may benefit from a reduced burden of ICRs, the general public benefits from the Agency's ability to provide these required reviews more quickly, resulting in increased public health and environmental protection.

Electronic reporting could minimize submission of unnecessary or duplicative reports in cases where facilities report to multiple government agencies and the agencies opt to rely on the EPA's electronic reporting system to view report submissions. Where air agencies continue to require a paper copy of these reports and will accept a hard copy of the electronic report, facilities will have the option to print paper copies of the electronic reporting forms to submit to the air agencies, and, thus, minimize the time spent reporting to multiple agencies. Additionally, maintenance and storage costs associated with retaining paper records could likewise be minimized by replacing those records with electronic records of electronically submitted data and reports.

Air agencies could benefit from more streamlined and automated review of the electronically submitted data. For example, because the performance test data would be readily-available in a standard electronic format, air agencies would be able to review reports and data electronically rather than having to conduct a review of the reports and data manually. Having reports and associated data in electronic format will facilitate review through the use of software ''search'' options, as well as the downloading and analyzing of data in spreadsheet format. Additionally, air agencies would benefit from the reported data being accessible to them through the EPA's electronic reporting system wherever and whenever they want or need access (as long as they have access to the Internet). The ability to access and review air emission report information electronically will assist air agencies to more quickly and accurately determine compliance with the applicable regulations, potentially allowing a faster response to violations which could minimize harmful air emissions. This benefits both air agencies and the general public.

The proposed electronic reporting of data is consistent with electronic data trends (*e.g.,* electronic banking and income tax filing). Electronic reporting of environmental data is already common practice in many media offices at the EPA. The changes being proposed in this rulemaking are needed to continue the EPA's transition to electronic reporting.

3. Startup, Shutdown, and Malfunction Requirements

In 2008, the United States Court of Appeals for the District of Columbia Circuit vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir.

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[28] Digital Government: Building a 21st Century Platform to Better Serve the American People, May 2012. Available at: *https://www.whitehouse.gov/sites/default/files/omb/egov/digital-government/digital-government-strategy.pdf.*

2008). Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some section 112 standards apply continuously.

While the current rule does not exempt periods of startup and shutdown from emissions standards, we are proposing several changes to eliminate the malfunction exemption that is contained in this rule. While, for simplicity, we refer throughout this section to the SSM exemption and the associated SSM plan requirements, only the malfunction exemption and its removal are relevant to this action because periods of startup and shutdown were never exempt from emissions standards in this subpart. As discussed earlier in this preamble (section IV.D.1), we are proposing standards in this rule that apply at all times (*i.e.,* to all batches), consistent with *Sierra Club* v. *EPA.* We are also proposing revisions to several provisions of 40 CFR part 63, subpart CCCC and to Table 6 to 40 CFR part 63, subpart CCCC (the General Provisions Applicability Table) as is explained in more detail below. For example, we are proposing to eliminate the incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are proposing to eliminate and revise certain recordkeeping and reporting requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully identified all such provisions and whether any of the identified provisions retain utility even in the absence of the SSM exemption.

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed alternate standards for those periods.

Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. In this NESHAP, owners and operators of nutritional yeast manufacturing facilities employ process controls to limit emissions. These process controls are employed from the time a fermenter starts production of a batch of yeast and continue until the fermenter is emptied of yeast. Additionally, emissions are averaged over the entire duration of each batch in order to meet emission limits, so there was no need to set separate limits for periods of startup and shutdown in this rule.

Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. 40 CFR 63.2 (definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards. Under CAA section 112, emissions standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing sources when setting emission standards. As the D.C. Circuit has recognized, the phrase ''average emissions limitation achieved by the best performing 12 percent of'' sources ''says nothing about how the performance of the best units is to be calculated.'' *Nat'l Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. A malfunction should not be treated in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a ''normal or usual manner'' and no statutory language compels EPA to consider such events in setting CAA section 112 standards.

Further, accounting for malfunctions in setting emission standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. *See, Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999) (''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.' '') *See* also, *Weyerhaeuser v Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

In this instance, it is unlikely that a malfunction would result in a violation of the standards for fermenters. For fermenters, the rule provides an option for owners and operators to determine the average VOC concentration for all batches within each fermentation stage using data from 12-month periods. This option minimizes the effect of malfunctions on the ability of a facility to meet the emission limits because the averaging effectively minimizes ''spikes'' in emissions. Additionally, many of the common malfunctions described by owners and operators of nutritional yeast manufacturing facilities during the site visits were malfunctions of the emissions monitoring equipment. While the equipment was unable to record accurate data during periods of malfunction, it did not impact actual emissions because process controls could still be used to limit emissions.

In the unlikely event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the Federal District Court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations.[29]

a. 40 CFR 63.2150 General Duty

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.6(e)(1)(i) does not apply to 40 CFR part 63, subpart CCCC. Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is no longer necessary or appropriate in light of the elimination of the SSM exemption. We are proposing instead to add general duty regulatory text at 40 CFR 63.2150(c) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The current language in 40 CFR 63.6(e)(1)(i) characterizes what the general duty entails during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty. Therefore, the language the EPA is proposing at 40 CFR 63.2150(c) does not include that language from 40 CFR 63.6(e)(1).

We are also proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.6(e)(1)(ii) does not apply to 40 CFR part 63, subpart CCCC. Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.2150.

b. SSM Plan

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.6(e)(3) does not apply to 40 CFR part 63, subpart CCCC. Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is proposing to remove the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance and thus the SSM plan requirements are no longer necessary.

c. Compliance With Standards

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.6(f)(1) does not apply to 40 CFR part 63, subpart CCCC. The current language of 40 CFR 63.6(f)(1) exempts sources from non-opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in this provision and held that the CAA requires that some section 112 standard apply continuously. Consistent with *Sierra Club,* the EPA is proposing standards in this rule that apply at all times.

d. 40 CFR 63.2161 Performance Testing

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.7(e)(1) does not apply to 40 CFR part 63, subpart CCCC. Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to add a performance testing requirement at 40 CFR 63.2161(b). The performance testing requirements we are proposing to add differ from the General Provisions performance testing provisions in several respects. The proposed regulatory text does not include the language in 40 CFR 63.7(e)(1) that restated the SSM exemption and language that precluded startup and shutdown periods from being considered ''representative'' for purposes of performance testing. The proposed performance testing provisions exclude periods of startup and shutdown. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during malfunctions because conditions during malfunctions are often not representative of normal operating conditions. The EPA is proposing to add language that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the owner or operator make available to the Administrator such records ''as may be necessary to determine the condition of the performance test'' upon request, but does not specifically require the information to be recorded. The regulatory text the EPA is proposing to add to this provision builds on that requirement and makes explicit the requirement to record the information.

e. Monitoring

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.8 (c)(1)(i) and (iii) do not apply to 40 CFR part 63, subpart CCCC. The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary in light of other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.8(d)(3) does not apply to 40 CFR part 63, subpart CCCC. The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement, which is no longer

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[29] *U.S. Sugar Corp.* v. *EPA,* No. 11–1108, 2016 U.S. App. LEXIS 13783, at *41–49 (D.C. Cir. July 29, 2016) (upholding EPA's approach to addressing periods of malfunction).

applicable. The EPA is proposing to add to the rule at 40 CFR 63.2182(b)(7) and 63.2183(d) text that contains the same requirements as 40 CFR 63.8(d)(3), except that the final sentence is replaced with the following sentence: ''The program of corrective action should be included in the plan required under § 63.8(d)(2).''

f. 40 CFR 63.2182 Recordkeeping

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(b)(2)(i) does not apply to 40 CFR part 63, subpart CCCC. Section 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. These recording provisions are no longer necessary because the EPA is proposing that recordkeeping and reporting applicable to normal operations will apply to startup and shutdown. In the absence of special provisions applicable to startup and shutdown, such as a startup and shutdown plan, there is no reason to retain additional recordkeeping for startup and shutdown periods.

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(b)(2)(ii) does not apply to 40 CFR part 63, subpart CCCC. Section 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. The EPA is proposing to add such requirements to 40 CFR 63.2182(a)(2). The regulatory text we are proposing to add differs from the General Provisions it is replacing in that the General Provisions requires the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment. The EPA is proposing that this requirement apply to any failure to meet an applicable standard and is requiring that the source record the date, time, and duration of the failure rather than the ''occurrence.''

The EPA is also proposing to add to 40 CFR 63.2182(a)(2) a requirement that sources keep records that include a list of the affected source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(b)(2)(iv) does not apply to 40 CFR part 63, subpart CCCC. When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable by reference to 40 CFR 63.2182(a)(2).

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(b)(2)(v) does not apply to 40 CFR part 63, subpart CCCC. When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(c)(15) does not apply to 40 CFR part 63, subpart CCCC. When applicable, the provision allows an owner or operator to use the affected source's SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan, specified in 40 CFR 63.6(e), to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12). The EPA is proposing to eliminate this requirement because SSM plans would no longer be required, and, therefore, 40 CFR 63.10(c)(15) no longer serves any useful purpose for affected units.

g. 40 CFR 63.2181 Reporting

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(d)(5) does not apply to 40 CFR part 63, subpart CCCC. Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is proposing to add reporting requirements to 40 CFR 63.2181(c)(5) and (6). The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as a stand-alone report. We are proposing language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semi-annual compliance report already required under this rule. We are proposing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We will no longer require owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because malfunction plans would no longer be required. The proposed amendments, therefore, eliminate the cross reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule from this section. These specifications are no longer necessary because the events will be reported in otherwise required reports with similar format and submittal requirements.

We are proposing to revise the General Provisions table (Table 6 to 40 CFR part 63, subpart CCCC) to specify that 40 CFR 63.10(d)(5)(ii) does not apply to 40 CFR part 63, subpart CCCC. Section 63.10(d)(5)(ii) describes an immediate report for startups, shutdowns, and malfunctions when a source failed to meet an applicable standard but did not follow the SSM plan. We will no longer require owners and operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan, because plans would no longer be required.

4. Rule Language Clarifications

We are proposing other miscellaneous revisions that add clarity to rule language. For example, we are using active, second-person voice throughout the rule by incorporating ''you must . . .'' into the language. This is consistent with the EPA's current rule-writing practices and creates uniformity within 40 CFR part 63, subpart CCCC. We are also proposing the removal of ''but is not limited to'' in 40 CFR 63.2132, because this language is not necessary. The 40 CFR part 63, subpart CCCC requirements are limited to fermenters at this time, and the removal of this language clarifies this distinction. The EPA requests comment on each of these proposed revisions.

E. What compliance dates are we proposing?

The EPA is proposing that currently operating facilities must immediately comply with the revised form of the fermenter VOC emission limits and general compliance requirements upon the effective date of the final rule. As discussed in section IV.D.2.a of this preamble, facilities that currently demonstrate compliance by monitoring brew ethanol in the fermenter have up to 1 year to install CEMS. During this time, emissions data must be collected for each batch using the existing compliance method (monitoring brew ethanol) for use in the semiannual compliance reports with the revised emission limits. Sources that are constructed or reconstructed after promulgation of the rule revisions must comply with the emission limits and compliance requirements upon startup of the affected source. We request comment on each of these timeframes.

We are proposing to revise 40 CFR 63.2133 to specify that an area source that becomes a major source of HAP, and that is an existing affected source, must be in compliance with the subpart by not later than 1 year after it becomes a major source, instead of by not later than 3 years. This revision is consistent with the proposed requirement that facilities have 1 year to install CEMS if they currently monitor brew ethanol in the fermenter to determine compliance. The EPA requests comment on this timeframe.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

We anticipate that four nutritional yeast facilities currently operating in the United States will be affected by these proposed amendments.

B. What are the air quality impacts?

The proposed amendments to this subpart will have a positive impact on air quality. While facilities will not need to install additional controls to comply with the proposed fermenter emission limits, the revisions will remove the exemption that allowed up to 2 percent of the total number of batches to exceed emission limits, as well as the exemption that allowed emissions from batches produced during periods of malfunction to not be used in determining compliance with emission limits. While these changes cannot easily be quantified due to a lack of data on the current number of exempted batches, the practical effect is that production of all batches of nutritional yeast at affected sources will be required to meet emission limits. The other proposed revisions, which affect testing, monitoring, recordkeeping, and reporting requirements, will ensure that emissions monitoring equipment continues to perform as expected and provides reliable data from each facility to be reported for compliance. For reference, the baseline emissions for each facility are documented in the memorandum, ''Emissions Data and Acute Risk Factor Used in Residual Risk Modeling: Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

C. What are the cost impacts?

We have estimated compliance costs for all existing sources to install the necessary monitoring equipment (*i.e.,* VOC CEMS) and perform annual RATAs for VOC CEMS. We estimated a total capital investment of $511,000 and an annualized cost of approximately $172,000. The details of the cost estimates are documented in the memorandum, ''Costs for the Manufacturing of Nutritional Yeast Source Category,'' which is available in the docket for this action.

D. What are the economic impacts?

Total annualized costs for this proposal are estimated to be $172,000. Estimated annualized compliance costs range from $16,000 to $109,000 per facility. The EPA conducted economic impact screening analyses for this proposal, as detailed in the memorandum, ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' which is available in the docket for this action. Screening analyses suggest that the impacts of this action will be minimal, with all entities subject to this action estimated to have cost-to-sales ratios of less than 0.1 percent. We do not expect any adverse economic impacts to result from this action.

E. What are the benefits?

As discussed above, the proposed amendments to this subpart will have positive impacts on air quality by removing the exemption for a portion of batches to meet emission limits. The proposed changes to monitoring methods will increase the reliability of emissions data collected by facilities by requiring continued maintenance of emission monitoring systems and monitoring of actual emission measurements at all times instead of allowing emission estimates based on brew ethanol correlations, which will allow regulators to clearly assess whether the standards for the protection of public health and the environment are being met. In particular, the demographics analysis shows that increased risk levels are concentrated around the facility that is not currently using CEMS. The proposed amendment will directly benefit this population by increasing the accuracy of the emissions data that is monitored and reported. Utilization of CEMS is also expected to facilitate more effective use of current process controls for acetaldehyde emissions versus use of the brew ethanol correlation approach. Other proposed amendments will result in additional benefits, such as streamlined reporting through electronic methods for owners/operators of nutritional yeast manufacturing facilities and increased access to emissions data by stakeholders, as described in previous sections.

VI. Request for Comments

We solicit comments on all aspects of this proposed action, including those aspects specifically called out elsewhere in this preamble. As noted previously, we are not seeking comment on the source category definition in this action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR Web site at *http://www.epa.gov/ttn/atw/rrisk/rtrpg.html*. The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any ''improved'' data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR Web site, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.
2. Fill in the commenter information fields for each suggested revision (*i.e.,* commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).
3. Gather documentation for any suggested emissions revisions (*e.g.,* performance test reports, material balance calculations).
4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA–HQ–OAR–2015–0730 (through the method described in the **ADDRESSES** section of this preamble).
5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at that facility. We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the RTR Web site at *http://www.epa.gov/ttn/atw/rrisk/rtrpg.html.*

VIII. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) that the EPA prepared has been assigned EPA ICR number 1886.03. A copy of the ICR can be found in the docket for this rule, and it is summarized here.

We are proposing new reporting and recordkeeping requirements to the Manufacturing of Nutritional Yeast source category as a result of additional requirements related to the use of CEMS.

Respondents/affected entities: Manufacturers of nutritional yeast.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart CCCC).

Estimated number of respondents: Four facilities.

Frequency of response: Initially and semiannually.

Total estimated burden: 1,340 hours (per year) for the responding facilities and 117 hours (per year) for the Agency. Of these, 43 hours (per year) for the responding facilities and 4 hours (per year) for the Agency is the incremental burden to comply with the proposed rule amendments. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $939,000 (per year), which includes $832,000 annualized capital and operation and maintenance costs, for the responding facilities and $5,400 (per year) for the Agency to comply with all of the requirements in this NESHAP. Of the total, $175,000 (per year), including $172,000 in annualized capital and operation and maintenance costs, for the responding facilities and $180 (per year) for the Agency, is the incremental cost to comply with the proposed amendments to this rule.

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.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than January 27, 2017. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. One entity subject to the requirements of this action is assumed to be a small business for the purposes of this analysis, as the complex ownership structure makes it difficult to clearly determine the entity's size. The Agency has determined that this entity may experience an impact of less than 0.01 percent of revenues. Details of this analysis are presented in the memorandum, ''Economic Impact Analysis for the Manufacturing of Nutritional Yeast Risk and Technology Review (RTR),'' which is available in the docket for this action.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate that may result in expenditures 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. The nationwide annualized cost of this action for affected industrial sources is estimated to be $172,000 per year.

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.

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

This action does not have tribal implications as specified in Executive Order 13175. No tribal facilities are known to be engaged in the nutritional yeast manufacturing industry that would be affected by this action. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. This action's health and risk assessments are contained in sections III.A and B and sections IV.A and B of this preamble.

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

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

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. Therefore, the EPA conducted a search to identify potentially applicable voluntary consensus standards. However, the Agency identified no such standards. Therefore, the EPA has decided to use EPA Method 25A of 40 CFR part 60, appendix A. A thorough summary of the search conducted and results are included in the memorandum titled, ''Voluntary Consensus Standard Results for the Risk and Technology Review of the Manufacturing of Nutritional Yeast NESHAP,'' which is available in the docket for this action.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (58 FR 7629, February 16, 1994).

The documentation for this decision is contained in section IV.A of this preamble and the technical report, ''Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Nutritional Yeast Manufacturing Facilities,'' which is available in the docket for this action.

As discussed in section IV.A of this preamble, we performed a demographic analysis, which is an assessment of risks to individual demographic groups, of the population close to the facilities (within 50 km and within 5 km). In this analysis, we evaluated the distribution of HAP-related cancer risks and non-cancer hazards from the nutritional yeast manufacturing facilities across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks.

The analysis indicates that the minority population living within 50 km (1,700,000 people, of which 41 percent are minority) and within 5 km (131,567 people, of which 68 percent are minority) of the four nutritional yeast manufacturing facilities is greater than the minority population found nationwide (28 percent). The specific demographics of the population within 5 and 50 km of the facilities indicate potential disparities in certain demographic groups, including the ''African American,'' ''Below the Poverty Level,'' and ''Over 25 and without high school diploma'' groups.

When examining the risk levels of those exposed to emissions from the four nutritional yeast manufacturing facilities we find approximately 750 persons around one facility (AB Mauri—Fleischmann's Yeast in Memphis, Tennessee) are exposed to a cancer risk greater than or equal to 1-in-1 million with the highest exposure to these individuals of less than 2-in-1 million. Of these 750 persons, 100 percent of them are defined as minority. When examining the noncancer risks surrounding these facilities, no one is predicted to have a chronic non-cancer TOSHI greater than 1. This facility is also the only one that is not currently using CEMS. The proposed amendments will directly benefit this population by increasing the accuracy of the emissions data that is monitored and reported. Utilization of CEMS is also expected to facilitate more effective use of process controls for acetaldehyde emissions versus use of the brew ethanol correlation approach.

The EPA has determined that this proposed rule does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples because the health risks based on actual emissions are low (below 2-in-1 million), the population exposed to risks greater than 1-in-1 million is relatively small (750 persons), and the rule maintains or increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority, low-income, or indigenous populations. Further, the EPA believes that implementation of this rule will provide an ample margin of safety to protect public health of all demographic groups.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: December 13, 2016.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend part 63 of title 40, chapter I, of the Code of Federal Regulations as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

§ 63.14 [Amended]

■ 2. Section 63.14 is amended by adding paragraph (m)(24) to read as follows:

* * * * *

(m) * * *

(24) EPA/600/R–12/531, EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, May 2012, IBR approved for § 63.2163(b)(2).

* * * * *

■ 3. Part 63 is amended by revising subpart CCCC to read as follows:

Subpart CCCC—National Emission Standards for Hazardous Air Pollutants: Manufacturing of Nutritional Yeast

Contents

Sec.

What This Subpart Covers

Emission Limitations

General Compliance Requirements

Testing and Initial Compliance Requirements

What This Subpart Covers

§ 63.2130 What is the purpose of this subpart?

This subpart establishes national emission limitations for hazardous air pollutants emitted from manufacturers of nutritional yeast. This subpart also establishes requirements to demonstrate initial and continuous compliance with the emission limitations.

§ 63.2131 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate a nutritional yeast manufacturing facility that is, is located at, or is part of a major source of hazardous air pollutants (HAP) emissions.

(1) A manufacturer of nutritional yeast is a facility that makes yeast for the purpose of becoming an ingredient in dough for bread or any other yeast-raised baked product, or for becoming a nutritional food additive intended for consumption by humans. A manufacturer of nutritional yeast does not include production of yeast intended for consumption by animals, such as an additive for livestock feed.

(2) A major source of HAP emissions is any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, any single HAP at a rate of 9.07 megagrams (10 tons) or more per year or any combination of HAP at a rate of 22.68 megagrams (25 tons) or more per year.

(b) [Reserved]

§ 63.2132 What parts of my plant does this subpart cover?

(a) This subpart applies to each new, reconstructed, or existing ''affected source'' that produces *Saccharomyces cerevisiae* at a nutritional yeast manufacturing facility.

(b) The affected source is the collection of equipment used in the manufacture of the nutritional yeast species *Saccharomyces cerevisiae.* This collection of equipment includes fermentation vessels (fermenters), as described in paragraph (c) of this section. The collection of equipment used in the manufacture of the nutritional yeast species *Candida utilis* (torula yeast) is not part of the affected source.

(c) The emission limitations in this subpart apply to fermenters in the affected source that meet all of the criteria listed in paragraphs (c)(1) and (2) of this section.

(1) The fermenters are ''fed-batch'' as defined in § 63.2192.

(2) The fermenters are used to support one of the last three fermentation stages in a production run (*i.e.,* third-to-last stage, second-to-last stage, and last stage), which may be referred to as ''stock, first generation, and trade,'' ''seed, semi-seed, and commercial,'' or ''CB4, CB5, and CB6'' stages.

(d) The emission limitations in this subpart do not apply to flask, pure-culture, yeasting-tank, or any other set-batch (defined in § 63.2192) fermentation, and they do not apply to any operations after the last dewatering operation, such as filtration.

(e) The emission limitations in Table 1 to this subpart do not apply to fermenters during the production of specialty yeast (defined in § 63.2192).

(f) An affected source is a ''new affected source'' if you commenced construction of the affected source after October 19, 1998, and you met the applicability criteria in § 63.2131 at the time you commenced construction.

(g) An affected source is ''reconstructed'' if it meets the criteria for reconstruction as defined in § 63.2.

(h) An affected source is ''existing'' if it is not new or reconstructed.

§ 63.2133 When do I have to comply with this subpart?

(a) If you have a new or reconstructed affected source, then you must comply with paragraph (a)(1) or (2) of this section.

(1) If you start up your affected source before May 21, 2001, then you must comply with the applicable emission limitations in Table 1 to this subpart no later than May 21, 2001.

(2) If you start up your affected source on or after May 21, 2001, then you must comply with the applicable emission limitations in Table 1 to this subpart upon startup of your affected source.

(b) If you have an existing affected source, then you must comply with the applicable emission limitations in Table 1 to this subpart no later than May 21, 2004.

(c) If you have an area source that increases its emissions, or its potential to emit, so that it becomes a major source of HAP, then paragraphs (c)(1) through (2) of this section apply.

(1) Any portion of the existing facility that is a new affected source or a new reconstructed source must be in compliance with this subpart upon startup.

(2) All other parts of the affected source must be in compliance with this subpart by not later than 1 year after it becomes a major source.

(d) You must meet the notification requirements in § 63.2180 according to the schedule in § 63.2180 and in subpart A of this part.

Emission Limitations

§ 63.2140 What emission limitations must I meet?

You must meet the applicable emission limitations in Table 1 to this subpart.

General Compliance Requirements

§ 63.2150 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limitations in Table 1 to this subpart at all times.

(b) If the date upon which you must demonstrate initial compliance as specified in § 63.2160 falls after the compliance date specified for your affected source in § 63.2133, then you must maintain a log detailing the operation and maintenance of the continuous emission monitoring systems and the process and emissions control equipment during the period between those dates.

(c) At all times, you must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether an affected source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator that may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the affected source.

(d) To determine compliance before [date of publication of the final rule in the **Federal Register**], you must monitor the volatile organic compound (VOC) concentration or brew ethanol continuously for each batch and demonstrate that the VOC concentration for at least 98 percent of the batches for each fermentation stage in each 12-month calculation period does not exceed the applicable emission limitations in Table 1 to this subpart. You must monitor VOC concentration either by installing and operating a continuous emission monitoring system (CEMS) to monitor VOC in the fermenter exhaust continuously or by monitoring the concentration of ethanol in the fermenter liquid continuously for each batch (*i.e.,* brew ethanol monitoring) and determining VOC concentration in the exhaust using the correlation equation developed according to § 63.2161.

(e) To determine compliance on or after [date of publication of the final rule in the **Federal Register**], you must monitor VOC concentration continuously for each batch and demonstrate compliance with the applicable emission limitations of either the Average Option or the Batch Option in Table 1 to this subpart. You must monitor VOC concentration by installing and operating a CEMS to monitor the VOC concentration in the fermenter exhaust continuously.

Testing and Initial Compliance Requirements

§ 63.2160 By what date must I conduct an initial compliance demonstration?

(a) For each emission limitation in Table 1 to this subpart for which you demonstrate compliance using the Average Option, you must demonstrate initial compliance for the period ending on the last day of the month that is 12 calendar months (or 11 calendar months, if the compliance date for your affected source is the first day of the month) after the compliance date that is specified for your affected source in § 63.2133. (For example, if the compliance date is October 15, 2017, then the first 12-month period for which you must demonstrate compliance would be October 15, 2017 through October 31, 2018.)

(b) For each emission limitation in Table 1 to this subpart for which you demonstrate compliance using the Batch Option, you must demonstrate initial compliance for the period ending June 30 or December 31 (use whichever date is the first date following the compliance date that is specified for your affected source in § 63.2133).

§ 63.2161 What performance tests and other procedures must I use if I monitor brew ethanol?

(a) You must conduct each performance test in Table 2 to this subpart that applies to you, as specified in paragraphs (b) through (f) of this section.

(b) You must conduct performance tests under such conditions as the Administrator specifies, based on representative performance of the affected source for the period being tested, and under the specific conditions that this subpart specifies in Table 2 to this subpart and in paragraphs (b)(1) through (4) of this section. You must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, you must make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(1) You must conduct each performance test simultaneously with brew ethanol monitoring to establish a brew-to-exhaust correlation as specified in paragraph (f) of this section.

(2) For each fermentation stage, you must conduct one run of the EPA Test Method 25A of 40 CFR part 60, appendix A–7, over the entire length of a batch. The three fermentation stages do not have to be from the same production run.

(3) You must obtain your test sample at a point in the exhaust-gas stream before you inject any dilution air. For fermenters, dilution air is any air not needed to control fermentation.

(4) You must record the results of the test for each fermentation stage.

(c) You may not conduct performance tests during periods of malfunction.

(d) You must collect data to correlate the brew ethanol concentration to the VOC concentration in the fermenter exhaust according to paragraphs (d)(1) through (3) of this section.

(1) You must collect a separate set of brew ethanol concentration data for each fed-batch fermentation stage while manufacturing the product that constitutes the largest percentage (by mass) of average annual production.

(2) You must measure brew ethanol as specified in § 63.2164 concurrently with conducting a performance test for VOC in fermenter exhaust as specified in paragraph (b) of this section. You must measure brew ethanol at least once during each successive 30-minute period over the entire period of the performance test for VOC in fermenter exhaust.

(3) You must keep a record of the brew ethanol concentration data for each fermentation stage over the period of EPA Test Method 25A of 40 CFR part 60, appendix A–7, performance test.

(e) For each set of data that you collected under paragraphs (b) and (d) of this section, you must perform a linear regression of brew ethanol concentration (percent) on VOC fermenter exhaust concentration (parts per million by volume (ppmv) measured as propane). You must ensure the correlation between the brew ethanol concentration, as measured by the brew ethanol monitor, and the VOC fermenter exhaust concentration, as measured by EPA Test Method 25A of 40 CFR part 60, appendix A–7, is linear with a correlation coefficient of at least 0.90.

(f) You must calculate the VOC concentration in the fermenter exhaust using the brew ethanol concentration data according to Equation 1 of this section.

$$BAVOC = BAE * CF + y \quad \text{(Eq. 1)}$$

Where:

BAVOC = Batch-average concentration of VOC in fermenter exhaust (ppmv measured as propane), calculated for compliance demonstration
BAE = Batch-average concentration of brew ethanol in fermenter liquid (percent), measured by the brew ethanol monitor
CF = Constant established at performance test and representing the slope of the regression line
Y = Constant established at performance test and representing the y-intercept of the regression line

§ 63.2162 When must I conduct subsequent performance tests?

(a) For each emission limitation in Table 1 to this subpart for which compliance is demonstrated by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in § 63.2161, you must conduct an EPA Test Method 25A of 40 CFR part 60, appendix A–7, performance test and establish a brew-to-exhaust correlation according to the procedures in Table 2 to this subpart and in § 63.2161, at least once every year.

(b) The first subsequent performance test must be conducted no later than 365 calendar days after the initial performance test conducted according to § 63.2160. Each subsequent performance test must be conducted no later than 365 calendar days after the previous performance test. You must conduct a performance test for each 365 calendar day period during which you demonstrate compliance using the brew ethanol correlation developed according to § 63.2161.

§ 63.2163 If I monitor fermenter exhaust, what are my monitoring installation, operation, and maintenance requirements?

(a) You must install and certify a CEMS that generates a single combined response value for VOC concentration (VOC CEMS) according to the procedures and requirements in Performance Specification 8—Performance Specifications for Volatile Organic Compound Continuous Emission Monitoring Systems in Stationary Sources in appendix B to part 60 of this chapter.

(b) You must operate and maintain your VOC CEMS according to the procedures and requirements in Procedure 1—Quality Assurance Requirements for Gas Continuous Emission Monitoring Systems Used for Compliance Determination in appendix F to part 60 of this chapter.

(1) You must conduct a relative accuracy test audit (RATA) at least annually, in accordance with sections 8 and 11, as applicable, of Performance Specification 8.

(2) As necessary, rather than relying on reference 2 of Performance Specification 8 of appendix B to 40 CFR part 60, you must rely on EPA/600/R–12/531, EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards, May 2012 (incorporated by reference, see § 63.14).

(3) Your affected source must meet the criteria of Performance Specification 8, section 13.2.

(c) You must use Method 25A in appendix A–7 to part 60 of this chapter as the Reference Method (RM).

(d) You must calibrate your VOC CEMS with propane.

(e) You must set your VOC CEMS span at less than 5 times the relevant VOC emission limitation given in Table 1 or 2 of this subpart. Note that the EPA considers 1.5 to 2.5 times the relevant VOC emission limitation to be the optimum range, in general.

(f) You must complete the performance evaluation and submit the performance evaluation report before the compliance date that is specified for your affected source in § 63.2133.

(g) You must monitor VOC concentration in fermenter exhaust at any point prior to dilution of the exhaust stream.

(h) You must collect data using the VOC CEMS at all times during each batch monitoring period, except for periods of monitoring system malfunctions, required monitoring system quality assurance or quality control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance.

(i) For each CEMS, you must record the results of each inspection, calibration, and validation check.

(j) You must check the zero (low-level) and high-level calibration drifts for each CEMS in accordance with the applicable Performance Specification of 40 CFR part 60, appendix B. You must adjust the zero (low-level) and high-level calibration drifts, at a minimum, whenever the zero (low-level) drift exceeds 2 times the limits of the applicable Performance Specification. You must perform the calibration drift checks at least once daily except under the conditions of paragraphs (j)(1) through (3) of this section.

(1) If a 24-hour calibration drift check for your CEMS is performed immediately prior to, or at the start of, a batch monitoring period of a duration exceeding 24 hours, you are not required to perform 24-hour-interval calibration drift checks during that batch monitoring period.

(2) If the 24-hour calibration drift exceeds 2.5 percent of the span value in fewer than 5 percent of the checks over a 1-month period, and the 24-hour calibration drift never exceeds 7.5 percent of the span value, you may reduce the frequency of calibration drift checks to at least weekly (once every 7 days).

(3) If, during two consecutive weekly checks, the weekly calibration drift exceeds 5 percent of the span value, then you must resume a frequency of at least 24-hour interval calibration checks until the 24-hour calibration checks meet the test of paragraph (j)(2) of this section.

(k) If your CEMS is out of control, you must take corrective action according to paragraphs (k)(1) through (3) of this section.

(1) Your CEMS is out of control if the zero (low-level) or high-level calibration drift exceeds 2 times the limits of the applicable Performance Specification.

(2) When the CEMS is out of control, you must take the necessary corrective action and repeat all necessary tests that indicate that the system is out of control. You must take corrective action and conduct retesting until the performance requirements are below the applicable limits.

(3) You must not use data recorded during batch monitoring periods in which the CEMS is out of control in averages and calculations used to demonstrate compliance, or to meet any data availability requirement established under this subpart. The beginning of the out-of-control period is the beginning of the first batch monitoring period that follows the most recent calibration drift check during which the system was within allowable performance limits. The end of the out-of-control period is the end of the last batch monitoring period before you have completed corrective action and successfully demonstrated that the system is within the allowable limits. If your successful demonstration that the system is within the allowable limits occurs during a batch monitoring period, then the out-of-control period ends at the end of that batch monitoring period. If the CEMS is out of control for any part of a particular batch monitoring period, it is out of control for the whole batch monitoring period.

§ 63.2164 If I monitor brew ethanol, what are my monitoring installation, operation, and maintenance requirements?

(a) You must install, operate, and maintain each brew ethanol monitor according to the manufacturer's specifications and in accordance with § 63.2150(c).

(b) Each of your brew ethanol monitors must complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 30-minute period within each batch monitoring period. Except as specified in paragraph (c) of this section, you must have a minimum of two cycles of operation in a 1-hour period to have a valid hour of data.

(c) You must reduce the brew ethanol monitor data to arithmetic batch averages computed from two or more data points over each 1-hour period, except during periods when calibration, quality assurance, or maintenance activities pursuant to provisions of this part are being performed. During these periods, a valid hour of data must consist of at least one data point representing a 30-minute period.

(d) You must have valid brew ethanol monitor data from all operating hours over the entire batch monitoring period.

(e) You must set the brew ethanol monitor span to correspond to not greater than 5 times the relevant emission limit; note that we consider 1.5 to 2.5 times the relevant emission limit to be the optimum range, in general. You must use the brew-to-exhaust correlation equation established under § 63.2161(f) to determine the span value for your brew ethanol monitor that corresponds to the relevant emission limit.

(f) For each brew ethanol monitor, you must record the results of each inspection, calibration, and validation check.

(g) The gas chromatographic (GC) that you use to calibrate your brew ethanol monitor must meet the requirements of paragraphs (g)(1) through (3) of this section.

(1) You must calibrate the GC at least daily, by analyzing standard solutions of ethanol in water (0.05 percent, 0.15 percent, and 0.3 percent).

(2) For use in calibrating the GC, you must prepare the standard solutions of ethanol using the procedures listed in paragraphs (g)(2)(i) through (vi) of this section.

(i) Starting with 100-percent ethanol, you must dry the ethanol by adding a small amount of anhydrous magnesium sulfate (granular) to 15–20 milliliters (ml) of ethanol.

(ii) You must place approximately 50 ml of water into a 100-ml volumetric flask and place the flask on a balance. You must tare the balance. You must weigh 2.3670 grams of the dry (anhydrous) ethanol into the volumetric flask.

(iii) Add the 100-ml volumetric flask contents to a 1000-ml volumetric flask. You must rinse the 100-ml volumetric flask with water into the 1000-ml flask. You must bring the volume to 1000 ml with water.

(iv) You must place an aliquot into a sample bottle labeled ‘‘0.3% Ethanol.’’

(v) You must fill a 50-ml volumetric flask from the contents of the 1000-ml flask. You must add the contents of the 50-ml volumetric flask to a 100-ml volumetric flask and rinse the 50-ml flask into the 100-ml flask with water. You must bring the volume to 100 ml with water. You must place the contents into a sample bottle labeled ‘‘0.15% Ethanol.’’

(vi) With a 10-ml volumetric pipette, you must add two 10.0-ml volumes of water to a sample bottle labeled ‘‘0.05% Ethanol.’’ With a 10.0-ml volumetric pipette, you must pipette 10.0 ml of the 0.15 percent ethanol solution into the sample bottle labeled ‘‘0.05% Ethanol.’’

(3) For use in calibrating the GC, you must dispense samples of the standard solutions of ethanol in water in aliquots to appropriately labeled and dated glass sample bottles fitted with caps having a Teflon® seal. You may keep refrigerated samples unopened for 1 month. You must prepare new calibration standards of ethanol in water at least monthly.

(h) You must calibrate the CEMS according to paragraphs (h)(1) through (3) of this section.

(1) To calibrate the brew ethanol monitor, you must inject a brew sample into a calibrated GC and compare the simultaneous ethanol value given by the brew ethanol monitor to that given by the GC. You must use either the Porapak® Q, 80–100 mesh, 6′ × 1⁄8′, stainless steel packed column or the DB Wax, 0.53 millimeter × 30 meter capillary column.

(2) If a brew ethanol monitor value for ethanol differs by 20 percent or more from the corresponding GC ethanol value, you must determine the brew ethanol values throughout the rest of the batch monitoring period by injecting brew samples into the GC not less frequently than once every 30 minutes. From the time at which you detect a difference of 20 percent or more until the batch monitoring period ends, the GC data will serve as the brew ethanol monitor data.

(3) You must perform a calibration of the brew ethanol monitor at least four times per batch.

§ 63.2165 How do I demonstrate initial compliance with the emission limitations if I monitor fermenter exhaust?

(a) You must demonstrate initial compliance with each emission limitation that applies to you according to Table 3 to this subpart.

(b) You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.2180(e).

Continuous Compliance Requirements

§ 63.2170 How do I monitor and collect data to demonstrate continuous compliance?

(a) You must monitor and collect data according to this section.

(b) Except for periods of monitoring system malfunctions, required monitoring system quality assurance or control activities (including, as applicable, calibration checks and required zero and span adjustments), and any scheduled maintenance, you must collect data using the CEMS at all times during each batch monitoring period.

(c) You may not use data recorded during monitoring malfunctions, associated repairs, and required quality assurance or quality control activities in data averages and calculations used to report emission or operating levels, or to fulfill a data collection requirement. You must use all the data collected during all other periods in assessing the operation of the control system.

(d) Any hour during the batch monitoring period for which quality-assured VOC data are not obtained is a deviation from monitoring requirements and is counted as an hour of monitoring system downtime.

§ 63.2171 How do I demonstrate continuous compliance with the emission limitations?

(a) You must demonstrate continuous compliance with each emission limitation in Table 1 to this subpart that applies to you according to methods specified in Table 4 to this subpart and the applicable procedures of this section.

(1) To demonstrate compliance prior to [date one year after the date of publication of the final rule in the **Federal Register**], you must install, operate, and maintain a CEMS in accordance with § 63.2163 to monitor VOC concentration in the fermenter exhaust or install, operate, and maintain a brew ethanol monitor in accordance with § 63.2164 to monitor the brew ethanol concentration in the fermenter liquid.

(2) To demonstrate compliance on and after [date 1 year after the date of publication of the final rule in the **Federal Register**], you must install, operate, and maintain a CEMS in accordance with § 63.2163 to monitor VOC concentration in the fermenter exhaust.

(b) To demonstrate compliance with emission limitations prior to [date of publication of the final rule in the **Federal Register**], you must calculate the percentage of within-concentration batches (defined in § 63.2192) for each 12-month calculation period by following the procedures in paragraphs (b)(1) through (4) of this section.

(1) You must determine the percentage of batches over a 12-month calculation period that were in compliance with the applicable maximum concentration. The total number of batches in the calculation period is the sum of the numbers of batches of each fermentation stage for which emission limits apply. To determine which batches are in the 12-month calculation period, you must

include those batches for which the batch monitoring period ended on or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

(2) You must determine the percentage of batches in compliance with the applicable emission limitations for each 12-month calculation period at the end of each calendar month.

(3) The first 12-month calculation period begins on the compliance date that is specified for your affected source in § 63.2133 and ends on the last day of the month that includes the date 1 year after your compliance date, unless the compliance date for your affected source is the first day of the month, in which case the first 12-month calculation period ends on the last day of the month that is 11 calendar months after the compliance date. (For example, if the compliance date for your affected source is October 15, 2017, the first 12-month calculation period would begin on October 15, 2017, and end on October 31, 2018. If the compliance date for your affected source is October 1, 2017, the first 12-month calculation period would begin on October 1, 2017, and end on September 30, 2018.)

(4) The second 12-month calculation period and each subsequent 12-month calculation period begins on the first day of the month following the first full month of the previous 12-month averaging period and ends on the last day of the month 11 calendar months later. (For example, if the compliance date for your affected source is October 15, 2017, the second calculation period would begin on December 1, 2017, and end on November 30, 2018.)

(c) To demonstrate compliance with emission limitations on and after [date of publication of the final rule in the **Federal Register**] by using the Average Option, you must follow the procedures in paragraphs (c)(1) through (3) of this section.

(1) At the end of each calendar month, you must determine the average VOC concentration from all batches in each fermentation stage in a 12-month calculation period. To determine which batches are in a 12-month calculation period, you must include those batches for which the batch monitoring period ended on or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

(2) The first 12-month calculation period begins on the compliance date that is specified for your affected source in § 63.2133 and ends on the last day of the month that includes the date 1 year after your compliance date, unless the compliance date for your affected source is the first day of the month, in which case the first 12-month calculation period ends on the last day of the month that is 11 calendar months after the compliance date. (For example, if the compliance date for your affected source is October 15, 2017, the first 12-month calculation period would begin on October 15, 2017, and end on October 31, 2018. If the compliance date for your affected source is October 1, 2017, the first 12-month calculation period would begin on October 1, 2017, and end on September 30, 2018.)

(3) The second 12-month calculation period and each subsequent 12-month calculation period begins on the first day of the month following the first full month of the previous 12-month averaging period and ends on the last day of the month 11 calendar months later. (For example, if the compliance date for your affected source is October 15, 2017, the second calculation period would begin on December 1, 2017, and end on November 30, 2018.)

(d) To demonstrate compliance with emission limitations on and after [date of publication of the final rule in the **Federal Register**] by using the Batch Option, you must determine the average VOC concentration in the fermenter exhaust for each batch of each fermentation stage in a semiannual reporting period (*i.e.,* January 1 through June 30 or July 1 through December 31). To determine which batches are in the semiannual reporting period, you must include those batches for which the batch monitoring period ended on or after midnight on the first day of the period and exclude those batches for which the batch monitoring period did not end before midnight on the last day of the period.

Notification, Reports, and Records

§ 63.2180 What notifications must I submit and when?

(a) You must submit all of the notifications in §§ 63.7(b) and (c), 63.8(e), (f)(4) and (6), and 63.9(b) through (h) that apply to you by the dates specified.

(b) If you start up your affected source before May 21, 2001, you are not subject to the initial notification requirements of § 63.9(b)(2).

(c) If you are required to conduct a performance test as specified in Table 2 to this subpart, you must submit a notification of intent to conduct a performance test at least 60 calendar days before the performance test is scheduled to begin as required in § 63.7(b)(1).

(d) If you are required to conduct a performance evaluation as specified in § 63.2163, you must submit a notification of the date of the performance evaluation at least 60 days prior to the date the performance evaluation is scheduled to begin as required in § 63.8(e)(2).

(e) If you are required to conduct a performance test as specified in Table 2 to this subpart, you must submit a Notification of Compliance Status according to § 63.9(h)(2)(ii).

(f) For each initial compliance demonstration required in Table 3 to this subpart, you must submit the Notification of Compliance Status no later than July 31 or January 31, whichever date follows the date that is specified for your affected source in § 63.2160(a) or (b). The first compliance report, described in § 63.2181(b)(1), serves as the Notification of Compliance Status.

§ 63.2181 What reports must I submit and when?

(a) You must submit each report in Table 5 to this subpart that applies to you.

(1) On and after [date of publication of the final rule in the **Federal Register**], you must also comply with electronic reporting for compliance tests as specified in paragraphs (a)(1)(i) and (ii) of this section.

(i) Within 60 days after the date of completing each performance test as required by this subpart, you must submit the results of the performance test following the procedure specified in either paragraph (a)(1)(i)(A) or (B) of this section.

(A) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (*https://www3.epa.gov/ttn/chief/ert/ert_info.html*) at the time of the test, you must submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*).) Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the EPA's ERT Web site. If you claim that some of the performance test information being submitted is confidential business information (CBI), then you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive or other commonly used electronic storage media to the EPA. The electronic media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(B) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 63.13.

(ii) Within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedure specified in either paragraph (ii)(A) or (B) of this section.

(A) For performance evaluations of CEMS measuring RATA pollutants that are supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the EPA via the CEDRI. Performance evaluation data must be submitted in a file format generated through the use of the EPA's ERT or an alternate file format consistent with the XML schema listed on the EPA's ERT Web site. If you claim that some of the performance evaluation information being submitted is CBI, then you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive or other commonly used electronic storage media to the EPA. The electronic storage media must be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(B) For any performance evaluations of continuous emission monitoring systems measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the evaluation, you must submit the results of the performance evaluation to the Administrator at the appropriate address listed in § 63.13.

(b) Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report by the date in Table 5 to this subpart and according to paragraphs (b)(1) through (5) of this section.

(1) The first compliance report must include the information specified in paragraph (c) of this section. If you are demonstrating compliance with an emission limitation using a 12-month calculation period (*e.g.,* the Average Option), then the first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.2133 and ending on either June 30 or December 31 (use whichever date is the first date following the end of the first 12 calendar months after the compliance date that is specified for your affected source in § 63.2133). (For example, if the compliance date for your affected source is October 15, 2017, then the first compliance report would cover the period from October 15, 2017 to December 31, 2018.) If you are demonstrating compliance with an emission limitation using the Batch Option, then the first compliance report must cover the period beginning on the compliance date that is specified for your affected source in § 63.2133 and ending on either June 30 or December 31 (use whichever date is the first date following the compliance date that is specified for your affected source in § 63.2133).

(2) The first compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date follows the end of the first compliance reporting period specified in paragraph (b)(1) of this section.

(3) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31. Each subsequent compliance report must include the information specified in paragraph (c) of this section.

(4) Each subsequent compliance report must be postmarked or delivered no later than July 31 or January 31, whichever date is the first date following the end of the semiannual reporting period.

(5) For each affected source that is subject to permitting regulations pursuant to 40 CFR part 70 or part 71, and if the permitting authority has established dates for submitting semiannual reports pursuant to 40 CFR 70.6(a)(3)(a)(iii)(A) or 40 CFR 71.6(a)(3)(a)(iii)(A), you may submit the first and subsequent compliance reports according to the dates the permitting authority has established instead of according to the dates in paragraphs (b)(1) through (4) of this section.

(c) The compliance report must contain the information listed in paragraphs (c)(1) through (7) of this section.

(1) Company name and address.

(2) Statement by a responsible official with that official's name, title, and signature, certifying the accuracy of the content of the report.

(3) Date of report and beginning and ending dates of the reporting period.

(4) For reporting periods ending before [date of publication of the final rule in the **Federal Register**], the percentage of batches that are within-concentration batches for each 12-month period ending on a calendar month that falls within the reporting period.

(5) For reporting periods ending before [date of publication of the final rule in the **Federal Register**], if an affected source fails to meet an applicable standard, the information for each batch for which the batch-average VOC concentration exceeded the applicable maximum VOC concentration in Table 1 to this subpart and whether the batch was in production during a period of malfunction or during another period.

(6) For reporting periods ending on or after [date of publication of the final rule in the **Federal Register**], if an affected source meets an applicable standard, the information in paragraph (c)(6)(i) or (ii) of this section, depending on the compliance option selected from Table 1 to this subpart.

(i) If using the Average Option in Table 1 to this subpart, the average VOC concentration in the fermenter exhaust from all batches in each fermentation stage for each 12-month period ending on a calendar month that falls within the reporting period that did not exceed the applicable emission limitation.

(ii) If using the Batch Option in Table 1 to this subpart, a certification that the average VOC concentration in the fermenter exhaust for each batch did not exceed applicable emission limitations.

(7) For reporting periods ending on and after [date of publication of the final rule in the **Federal Register**], if an affected source fails to meet an applicable standard, the information in paragraph (c)(7)(i) or (ii) of this section, depending on the compliance option selected from Table 1 to this subpart.

(i) If using the Average Option in Table 1 to this subpart, the average VOC concentration in the fermenter exhaust from all batches in each fermentation stage for each 12-month period that failed to meet the applicable standard, the fermenters that operated in each fermentation stage that failed to meet the applicable standard, the duration of each failure, an estimate of the quantity of VOC emitted over the emission limitation, a description of the method used to estimate the emissions, and the actions taken to minimize emissions and correct the failure.

(ii) If using the Batch Option in Table 1 to this subpart, the fermenters and batches that failed to meet the applicable standard; the date, time, and duration of each failure; an estimate of the quantity of VOC emitted over the emission limitation; a description of the method used to estimate the emissions; and the actions taken to minimize emissions and correct the failure.

(8) The total operating hours and hours of monitoring system downtime for each fermenter.

§ 63.2182 What records must I keep?

(a) You must keep the records listed in paragraphs (a)(1) through (4) of this section.

(1) A copy of each notification and report that you submitted to comply with this subpart, including all documentation supporting any Notification of Compliance Status and compliance report that you submitted, according to the requirements in § 63.10(b)(2)(xiv).

(2) Records of failures to meet a standard, specified in § 63.2181(c)(5) and (7).

(3) Records of performance tests and performance evaluations as required in § 63.10(b)(2)(viii).

(4) Records of results of brew-to-exhaust correlation tests specified in § 63.2161.

(b) For each CEMS, you must keep the records listed in paragraphs (b)(1) through (9) of this section.

(1) Records described in § 63.10(b)(2)(vi).

(2) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, CEMS data, raw performance testing measurements, and raw performance evaluation measurements that support data that you are required to report).

(3) Records described in § 63.10(b)(2)(viii) through (xi). The CEMS system must allow the amount of excess zero (low-level) and high-level calibration drift measured at the interval checks to be quantified and recorded.

(4) All required CEMS measurements (including monitoring data recorded during CEMS breakdowns and out-of-control periods).

(5) Identification of each time period during which the CEMS was inoperative, except for zero (low-level) and high-level checks.

(6) Identification of each time period during which the CEMS was out of control, as defined in § 63.2163(k).

(7) Current version of the performance evaluation test plan, as specified in § 63.8(d)(2), including the program of corrective action for a malfunctioning CEMS, and previous (*i.e.,* superseded) versions of the performance evaluation test plan for a period of 5 years after each revision to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(8) Request for alternatives to relative accuracy test audits for CEMS as required in § 63.8(f)(6)(i).

(9) Records of each deviation from monitoring system requirements, including a description and explanation of each deviation.

(c) You must keep the records required in Table 4 to this subpart to show continuous compliance with each emission limitation that applies to you.

(d) You must also keep the records listed in paragraphs (d)(1) through (3) of this section for each batch in your affected source.

(1) Unique batch identification number.

(2) Fermentation stage for which you are using the fermenter.

(3) Unique CEMS equipment identification number.

§ 63.2183 In what form and how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review, according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record on site for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). You may keep the records off site for the remaining 3 years.

(d) You must keep written procedures documenting the CEMS quality control program on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, to be made available for inspection, upon request, by the Administrator.

Other Requirements and Information

§ 63.2190 What parts of the General Provisions apply to me?

Table 6 to this subpart shows which parts of the General Provisions in §§ 63.1 through 63.13 apply to you.

§ 63.2191 Who implements and enforces this subpart?

(a) We, the U.S. EPA, or a delegated authority such as your state, local, or tribal agency, can implement and enforce this subpart. If our Administrator has delegated authority to your state, local, or tribal agency, then that agency has the authority to implement and enforce this subpart. You should contact the U.S. EPA Regional Office that serves you to find out if this subpart is delegated to your state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by our Administrator and are not transferred to the state, local, or tribal agency.

(c) The authorities that will not be delegated to state, local, or tribal agencies are listed in paragraphs (c)(1) through (4) of this section.

(1) Approval of alternatives to the non-opacity emission limitations in § 63.2140 under § 63.6(g).

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f) and as defined in § 63.90.

(3) Approval of major alternatives to monitoring under § 63.8(f) and as defined in § 63.90.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f) and as defined in § 63.90.

§ 63.2192 What definitions apply to this subpart?

Terms used in this subpart are defined in the Clean Air Act, in 40 CFR 63.2, the General Provisions of this part, and in this section as follows:

Batch means a single fermentation cycle in a single fermentation vessel (fermenter).

Batch monitoring period means the period that begins at the later of either the start of aeration or the addition of yeast to the fermenter; the period ends at the earlier of either the end of aeration or the point at which the yeast has begun being emptied from the fermenter.

Brew means the mixture of yeast and additives in the fermenter.

Brew ethanol means the ethanol in fermenter liquid.

Brew ethanol monitor means the monitoring system that you use to measure brew ethanol to demonstrate compliance with this subpart. The monitoring system includes a resistance element used as an ethanol sensor, with the measured resistance proportional to the concentration of ethanol in the brew.

Brew-to-exhaust correlation means the correlation between the concentration of ethanol in the brew and the concentration of VOC in the fermenter exhaust. This correlation is specific to each fed-batch fermentation stage and is established while manufacturing the product that comprises the largest percentage (by mass) of average annual production.

Emission limitation means any emission limit or operating limit.

Fed-batch means the yeast is fed carbohydrates and additives during fermentation in the vessel.

Monitoring system malfunction means any sudden, infrequent, and not reasonably preventable failure of the monitoring system to provide valid data. Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to complete monitoring system repairs in response to monitoring system malfunctions and to return the monitoring system to operation as expeditiously as practicable.

1-hour period means any 60-minute period commencing on the minute at which the batch monitoring period begins.

Product means the yeast resulting from the final stage in a production run. Products are distinguished by yeast species, strain, and variety.

Responsible official means responsible official as defined in 40 CFR 70.2.

Set-batch means the yeast is fed carbohydrates and additives only at the start of the batch.

Specialty yeast includes but is not limited to yeast produced for use in wine, champagne, whiskey, and beer.

Within-concentration batch means a batch for which the average VOC concentration is not higher than the maximum concentration that is allowed as part of the applicable emission limitation.

TABLE 1 TO SUBPART CCCC OF PART 63—EMISSION LIMITATIONS

For each fed-batch fermenter producing yeast in the following fermentation stage . . .	Before [date of publication of the final rule in the **Federal Register**] . . .	On and after [date of publication of the final rule in the **Federal Register**], you must comply with either the Average Option or the Batch Option . . .	
	You must not exceed the following VOC emission limitation[a] . . .	Average Option: You must not exceed the following VOC emission limitation[a] . . .	Batch Option: You must not exceed the following VOC emission limitation[a] . . .
Last stage	100 parts per million by volume (ppmv) (measured as propane) in the fermenter exhaust for at least 98 percent of all batches[b] in each 12-month calculation period described in § 63.2171(b).	95 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust from all batches[b] in this stage in each 12-month calculation period[c].	100 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust for each batch.[b]
Second-to-last stage	200 ppmv (measured as propane) in the fermenter exhaust for at least 98 percent of all batches[b] in each 12-month calculation period described in § 63.2171(b).	190 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust from all batches[b] in this stage in each 12-month calculation period[c].	200 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust for each batch.[b]
Third-to-last stage	300 ppmv (measured as propane) in the fermenter exhaust for at least 98 percent of all batches[b] in each 12-month calculation period described in § 63.2171(b).	285 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust from all batches[b] in this stage in each 12-month calculation period[c].	300 ppmv (measured as propane) for the average VOC concentration in the fermenter exhaust for each batch.[b]

[a] The emission limitation does not apply during the production of specialty yeast.

[b] The average VOC concentration for each batch equals the average VOC concentration over the duration of a batch.

[c] Determined as the average of all batch-average VOC concentration data for this stage in each 12-month calculation period as described in §§ 63.2160(a) and 63.2171(c).

TABLE 2 TO SUBPART CCCC OF PART 63—REQUIREMENTS FOR PERFORMANCE TESTS IF YOU MONITOR BREW ETHANOL

For each fed-batch fermenter for which compliance is determined by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in § 63.2161, you must . . .	Using . . .	According to the following requirements . . .
Measure VOC as propane	Method 25A[a], or an alternative validated by EPA Method 301[b] and approved by the Administrator.	You must measure the VOC concentration in the fermenter exhaust at any point prior to the dilution of the exhaust stream.

[a] EPA Test Method 25A is found in appendix A–7 of 40 CFR part 60.

[b] EPA Test Method 301 is found in appendix A of 40 CFR part 63.

TABLE 3 TO SUBPART CCCC OF PART 63—INITIAL COMPLIANCE WITH EMISSION LIMITATIONS

For . . .	Before [date of publication of the final rule in the **Federal Register**], you have demonstrated initial compliance if . . .	On and after [date of publication of the final rule in the **Federal Register**] . . .	
		Average Option: You have demonstrated initial compliance if . . .	Batch Option: You have demonstrated initial compliance if . . .
Each fed-batch fermenter producing yeast in a fermentation stage (last (Trade), second-to-last (First Generation), or third-to-last (Stock)) for which compliance is determined by monitoring VOC concentration in the fermenter exhaust.	The average VOC concentration in the fermenter exhaust for at least 98 percent of the batches (sum of batches from last, second-to-last, and third-to-last stages) during the initial compliance period does not exceed the applicable maximum concentration in Table 1 to this subpart.	The average VOC concentration in the fermenter exhaust from all batches in each fermentation stage during the initial compliance period described in § 63.2160(a) does not exceed the applicable concentration in Table 1 to this subpart.	The average VOC concentration in the fermenter exhaust for each batch of each fermentation stage during the initial compliance period described in § 63.2160(b) does not exceed the applicable concentration in Table 1 to this subpart.

TABLE 4 TO SUBPART CCCC OF PART 63—CONTINUOUS COMPLIANCE WITH EMISSION LIMITATIONS

For . . .	Before [date of publication of the final rule in the **Federal Register**], you must demonstrate continuous compliance by . . .	On and after [date of publication of the final rule in the **Federal Register**] . . .	
		Average Option: You must demonstrate continuous compliance by . . .	Batch Option: You must demonstrate continuous compliance by . . .
1. Each fed-batch fermenter producing yeast in a fermentation stage (last (Trade), second-to-last (First Generation), or third-to-last (Stock)) for which compliance is determined by monitoring VOC concentration in the fermenter exhaust.	Showing that for at least 98 percent of the batches (sum of batches from last, second-to-last, and third-to-last stages) for each 12-month period ending within a semiannual reporting period described in § 63.2181(b)(3), the batch-average VOC concentration in the fermenter exhaust does not exceed the applicable maximum concentration in Table 1 to this subpart.	Showing that the average VOC concentration in the fermenter exhaust from all batches in each fermentation stage during each 12-month calculation period ending within a semiannual reporting period described in § 63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart.	Showing that the average VOC concentration in the fermenter exhaust for each batch within a semiannual reporting period described in § 63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart.
2. Each fed-batch fermenter producing yeast in a fermentation stage (last (Trade), second-to-last (First Generation), or third-to-last (Stock)) for which compliance is determined by monitoring brew ethanol concentration and calculating VOC concentration in the fermenter exhaust according to the procedures in § 63.2161.	Showing that for at least 98 percent of the batches (sum of batches from last, second-to-last, and third-to-last stages) for each 12-month period ending within a semiannual reporting period described in § 63.2181(b)(3), the batch-average VOC concentration in the fermenter exhaust does not exceed the applicable maximum concentration in Table 1 to this subpart.	Showing that the average VOC concentration in the fermenter exhaust from all batches in each fermentation stage during each 12-month calculation period ending within a semiannual reporting period described in § 63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart [a].	Showing that the average VOC concentration in the fermenter exhaust for each batch within a semiannual reporting period described in § 63.2181(b)(3) does not exceed the applicable concentration in Table 1 to this subpart.[a]

[a] Monitoring brew ethanol to demonstrate compliance is not allowed on and after [date one year after the date of publication of the final rule in the **Federal Register**], as specified in § 63.2171(a)(2).

TABLE 5 TO SUBPART CCCC OF PART 63—REQUIREMENTS FOR REPORTS

You must submit a . . .	The report must contain . . .	You must submit the report . . .
1. Compliance report	a. The information described in § 63.2181(c), for 12-month calculation periods ending on each calendar month that falls within the reporting period.	Semiannually according to the requirements in § 63.2181(b).
	b. If you had a malfunction during the reporting period, then the compliance report must include the information in § 63.2181(c)(5) and (7).	Semiannually according to the requirements in § 63.2181(b).
2. Performance Evaluation Report	The results of the performance evaluation, including information from the performance evaluation plan at 63.8(e)(3).	At least annually and according to the requirements in §§ 63.2163(f) and 63.2181(a)(1)(ii).

TABLE 6 TO SUBPART CCCC OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART CCCC

Citation	Subject	Applicable to subpart CCCC?
§ 63.1	Applicability	Yes.
§ 63.2	Definitions	Yes.
§ 63.3	Units and Abbreviations	Yes.
§ 63.4	Prohibited Activities and Circumvention	Yes.
§ 63.5	Construction and Reconstruction	Yes.
§ 63.6	Compliance With Standards and Maintenance Requirements.	1. § 63.6(e)(1)(i) does not apply, instead specified in § 63.2150(c). 2. § 63.6(e)(1)(ii), (e)(3), (f)(1), and (h) do not apply. 3. Otherwise, all apply.
§ 63.7	Performance Testing Requirements	1. § 63.7(a)(1)–(2) do not apply, instead specified in § 63.2162. 2. § 63.7(e)(1) and (e)(3) do not apply, instead specified in § 63.2161(b). 3. Otherwise, all apply.
§ 63.8	Monitoring Requirements	1. § 63.8(a)(2) is modified by § 63.2163. 2. § 63.8(d)(3) does not apply, instead specified in § 63.2182(b)(7) and § 63.2183(d). 3. § 63.8(a)(4), (c)(1)(i), (c)(1)(iii), (c)(4)(i), (c)(5), (e)(5)(ii), and (g)(5) do not apply. 4. § 63.8(c)(4)(ii), (c)(6)–(8), (e)(4), and (g)(1)–(4) do not apply, instead specified in § 63.2163, § 63.2170(b), and § 63.2182(b)(6). 5. Otherwise, all apply.
§ 63.9	Notification Requirements	1. § 63.9(b)(2) does not apply because rule omits requirements for initial notification for affected sources that start up prior to May 21, 2001. 2. § 63.9(f) does not apply. 3. Otherwise, all apply.
§ 63.10	Recordkeeping and Reporting Requirements.	1. § 63.10(b)(2)(ii) does not apply, instead specified in § 63.2182(a)(2). 2. § 63.10(c)(1)–(6) do not apply, instead specified in § 63.2182(b)(4)–(6). 3. § 63.10 (b)(2)(i), (b)(2)(iv), (b)(2)(v), (c)(15), (d)(3), (e)(2)(ii), and (e)(3)–(4) do not apply. 4. § 63.10(d)(5) does not apply, instead specified in § 63.2181(c)(5) and (7). 5. Otherwise, all apply.
§ 63.11	Flares	No.
§ 63.12	Delegation	Yes.
§ 63.13	Addresses	Yes.
§ 63.14	Incorporation by Reference	Yes.
§ 63.15	Availability of Information	Yes.

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