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Subject: Hazardous Air Pollutant List; Modification

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ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 63

[AD-FRL-5520-5]
RIN 2060-AF33

Hazardous Air Pollutant List; Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is amending the list of hazardous air pollutants in Clean Air Act Section 112(b)(1) by removing the compound caprolactam (CAS No. 105-60-2). This rulemaking was initiated in response to a petition to delete the substance caprolactam which was filed by AlliedSignal, Inc., BASF Corporation, and DSM Chemicals North

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America under section 112(b)(3) of the Act. Based on the available information concerning the potential hazards of and projected exposures to caprolactam, EPA has made a determination pursuant to Clean Air Act Section 112(b)(3)(C) that there are adequate data on the health and environmental effects of caprolactam to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the compound

may not be reasonably anticipated to cause adverse human health or environmental effects. Although EPA acknowledges that there are scientific uncertainties in its analysis of the potential effects of ambient caprolactam exposures, EPA does not regard any of these uncertainties to be sufficiently material to preclude this determination.

DATES: This final rule will be effective on June 18, 1996. Because this final rule is based on a determination of nationwide scope and effect, any petition for judicial review of this rule may be filed only in the United States Court of Appeals for the District of Columbia and must be filed no later than August 19, 1996.

ADDRESSES: The administrative record supporting this final rule is collected in Docket Number A-94-33. All documents in that docket, including a complete copy of the original petition, all comments on the proposed rule, and a transcript of the public hearing, may be examined between 8:00 A.M. and 4:30 P.M. on business days at the EPA Central Docket Section, Waterside Mall, 401 M St., SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: For specific information concerning this final rule, contact Dr. Nancy B. Pate, Office of Air Quality Planning and Standards (MD-12), U.S. EPA, Research Triangle Park, NC 27711, telephone (919) 541-5347.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. The Delisting Process

Section 112 of the Clean Air Act contains a mandate for EPA to evaluate and control emissions of hazardous air pollutants. Section 112(b)(1) includes an initial list of hazardous air pollutants that is composed of specific chemical compounds and compound classes to be used to identify source categories for which the EPA will subsequently promulgate emissions standards.

Clean Air Act Section 112(b)(2) requires EPA to make periodic revisions to the initial list of hazardous air pollutants set forth in Section 112(b)(1) and outlines criteria to be applied in deciding whether to add or delete particular substances. Section 112(b)(2) identifies pollutants that should be listed as:

* * * pollutants which present, or may present, through

inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise * * *

To assist EPA in making judgments about whether a pollutant causes an adverse environmental effect, Section 112(a)(7) defines an ``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.

Section 112(b)(3) establishes general requirements for petitioning EPA to modify the hazardous air pollutant list by adding or deleting a substance. Although the Administrator may add or delete a substance on his own initiative, the burden is on a petitioner to include sufficient information to support the requested addition or deletion under the substantive criteria set forth in Sections 112(b)(3) (B) and (C). The Administrator must either grant or deny a petition within 18 months of receipt. If the Administrator decides to grant a petition, the Agency publishes a written explanation of the Administrator's decision, along with a proposed rule to add or delete the substance. If the Administrator decides to deny the petition, the Agency publishes a written explanation of the basis for denial. A decision to deny a petition is final Agency action subject to review in the D.C. Circuit Court of Appeals under Clean Air Act Section 307(b).

To promulgate a final rule deleting a substance from the hazardous air pollutant list, Section 112(b)(3)(C) provides that the Administrator must determine that:

* * * there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

EPA will grant a petition to delete a substance, and publish a proposed rule to delete that substance, if it makes an

initial determination that this criterion has been met. After affording an opportunity for comment and for a hearing, EPA will make a final determination whether the criterion has been met.

EPA does not interpret Section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list. The use of the terms ``adequate'' and ``reasonably'' indicate that the Agency must weigh the potential uncertainties and their likely significance. Uncertainties concerning the risk of adverse health or environmental effects may be mitigated if EPA can determine that projected exposures are sufficiently low to provide reasonable assurance that such adverse effects will not occur. Similarly, uncertainties concerning the magnitude of projected exposures may be mitigated if EPA can determine that the levels which might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels. However, the burden remains on a petitioner to resolve any critical uncertainties associated with missing information. EPA will not grant a petition to delete a substance if there are major uncertainties which need to be addressed before EPA would have sufficient information to make the requisite determination.

B. The Present Petition and Rulemaking

On July 19, 1993, EPA received a petition from AlliedSignal, Inc., BASF Corporation, and DSM Chemicals North America, Inc. (``petitioners'') to delete caprolactam (CAS No. 105-60-2) from the hazardous air pollutant list in Section 112(b)(1). Following receipt of the petition, EPA conducted a preliminary evaluation to determine whether the petition was complete according to Agency criteria. To be deemed complete, a petition must consider all available health and environmental effects data. A petition must also provide emissions data sufficient to assess peak and average emissions for each source, and must estimate the resultant exposures of people living in the vicinity of the source. In addition, a petition must address the environmental impacts associated with emissions to the ambient air and impacts associated with the subsequent cross-media transport of those emissions. EPA found the petition to delete caprolactam to be complete and published a notice of receipt and request for comments in the Federal

Register on August 26, 1993 (58 FR 45081).

After evaluating submissions received by EPA in response to the notice of receipt, which included concerns expressed by citizens concerning emissions of caprolactam by the AlliedSignal facility in Irmo, South Carolina, EPA entered into discussions with AlliedSignal to determine what could be done to address these concerns. On March 13, 1995, EPA executed two detailed emission reduction agreements with AlliedSignal concerning the Irmo manufacturing facility and another facility located in Chesterfield, Virginia, copies of which are included in the public docket for this rulemaking. Under these agreements, AlliedSignal is installing emission controls for caprolactam which EPA believes are equivalent to the controls which would have been required had EPA issued a standard to control these sources under Section 112. The agreed emission controls will be incorporated in federally enforceable operating permits for the affected facilities, and will be in place years earlier than controls would have otherwise been required. In addition, AlliedSignal has established a citizen advisory panel concerning the Irmo facility, which EPA is hopeful will improve communications with the community and provide citizens an ongoing role in implementation of the agreed emission reductions.

On September 8, 1995, based on a comprehensive review of the data provided in the petition and otherwise provided to EPA, the Agency made an initial determination that the statutory criterion for deletion of caprolactam from the hazardous air pollutant list had been met. EPA therefore granted the petition by AlliedSignal, Inc., BASF Corporation, and DSM Chemicals and issued a proposed rule to delist caprolactam. (60 FR 48081, September 18, 1995).

EPA received a total of 19 comments on the September 18, 1995 proposed rule. EPA subsequently granted a request by a citizen's group concerned about emissions from the AlliedSignal Irmo, SC facility to extend the comment period until November 2, 1995. (60 FR 58589, November 28, 1995). EPA conducted this delisting rulemaking pursuant to the procedures established by Clean Air Act Section 307(d). Accordingly, as provided by Section 307(d)(5), EPA held a public hearing concerning the proposed rule in Irmo, SC on December 7, 1995. A transcript of the hearing is included in the public docket for this rulemaking. Pursuant to Section 307(d)(5), EPA kept the record of this rulemaking open for thirty days after the December 7, 1995 hearing to receive rebuttal and supplementary information.

II. Adverse Comments and EPA Responses

A. Overview

Of the 19 written comments which were received concerning the proposed delisting of caprolactam, seven commenters supported and seven commenters opposed delisting. Other commenters expressed concerns regarding particular elements of the Agency's assessment, but did not expressly support or oppose the proposal. Many of the persons who made statements at the public hearing held on December 7, 1995 in Irmo, SC expressed opposition to the proposed delisting, in most cases because of a belief that emissions by AlliedSignal's Irmo facility were the cause of adverse health effects in their homes or community. Many of the commenters opposing the delisting of caprolactam were members or representatives of People United for a Responsible Environment (PURE), a citizen's group located in the Irmo-St. Andrews area of Columbia, SC.

EPA has considered carefully all of the comments both supporting and opposing the proposed delisting, focussing in particular on those comments which suggested potential deficiencies in the substantive rationale upon which EPA based its initial determination that the criterion in Clean Air Act Section 112(b)(3)(C) had been met. A summary of the comments and the EPA responses to them has been included in the docket for this proceeding. In this notice, EPA will discuss adverse comments which it received and its response to them.

B. Toxicity Data

Opponents of delisting commented that EPA should place greater emphasis on the findings in several Eastern European studies, which reported adverse reproductive effects in animals and exposed workers following inhalation of caprolactam. Unfortunately, there are numerous methodologic problems with the manner in which the cited studies were performed and documented which severely limit their value for risk assessment. Well-designed, documented and conducted animal studies do indicate that the most sensitive chronic health effect endpoint associated with caprolactam exposure is reduced mean fetal body weight (noted in a rodent reproductive study). However, since the reported results in these Eastern European studies cannot be readily reconciled with subsequent studies, EPA does not believe that these studies warrant any change in its risk assessment for caprolactam.

Opponents of delisting also have argued that the available animal data on inhalation of caprolactam is inadequate to

support the Agency's conclusions, and that EPA should wait for the results from the subchronic rat inhalation study of caprolactam which AlliedSignal is currently performing before taking final action in this rulemaking. EPA agrees that the available animal data on inhalation of caprolactam is very limited in comparison to the large number of studies of caprolactam ingestion. This is largely because the physical properties of the substance make it difficult to generate stable atmospheres of caprolactam at levels which would be toxicologically significant and to control for possible secondary exposure to caprolactam by the oral route. However, EPA believes that the commenters who assert that EPA should wait to take action until after the current subchronic inhalation study has been completed misunderstand the study's purpose and likely significance.

Based on the currently available human and animal data, the most sensitive effect of inhalation exposure to caprolactam is irritation of the eye, nose, and throat. In a limited but reliable occupational study of workers exposed to airborne caprolactam over nearly two decades, irritant effects in the nose and throat were observed in some workers at all levels above 46 mg/m<SUP>3, and no distress was noted among workers at concentrations ranging up to 32 mg/m<SUP>3. This approximate no observed effect level of 32 mg/m<SUP>3 for acute irritation by caprolactam in humans is consistent with one animal study, in which brief exposure to caprolactam levels up to 26 mg/m<SUP>3 did not elicit any of the physiologic responses typical of irritants.

EPA believes that projected exposures of the general population to a substance in the ambient air at concentrations which result in acute irritation can be an appropriate basis for inclusion of that substance on the list of hazardous air pollutants. However, in the case of caprolactam, the highest modeled one-hour caprolactam concentration near any facility based on reported emissions was approximately 1 mg/ m<SUP>3, well below the lowest documented irritation level of 46 mg/ m<SUP>3.

The target exposure levels in the subchronic inhalation study being conducted by AlliedSignal are 25, 75,

and 250 mg/m<SUP>3. The new inhalation study will provide additional information on potential adverse effects on the respiratory tract, as well as any adverse systemic effects, associated with sustained inhalation of caprolactam. Although EPA is reluctant to make quantitative comparisons between the oral and inhalation routes, EPA has previously calculated

that the oral NOAEL (No Observed Adverse Effect Level) for reproductive effects of 50 mg/kg/day would be approximately equivalent to 175 mg/m<SUP>3, after adjusting for a human body weight of 70 kg, 100 percent absorption, and a human inhalation rate of 20 m<SUP>3/day. EPA considers it probable that the new inhalation study will permit better quantification of the dose-response relationship for potential portal of entry effects, but it is less clear whether even the highest concentration achieved by the new study will be sufficient to cause any of the systemic effects observed in previous oral studies.

The purpose of the new inhalation study is to enable a more precise quantitative dose response assessment for the inhalation effects of caprolactam exposure. While the study may be quite useful in this respect, EPA considers it unlikely that the study will change the more general conclusions of the risk assessment on which this final rule is based. In other words, EPA does not consider the uncertainties the new study is designed to address to be material to the overall risk determination underlying today's action.

Even if the new study were to detect portal of entry effects in rats following repeated exposure at the lowest target concentration of 25 mg/m<SUP>3, this would probably have greater significance in an occupational context than in assessing the risks associated with ambient exposures. The new study will expose animals to this concentration for 13 weeks. The maximum modeled ambient caprolactam concentration for a 24-hour period is 0.25 mg/m<SUP>3, two orders of magnitude below the lowest target concentration in the new study. (The maximum modeled ambient concentration on an annual basis is 0.05 mg/ m<SUP>3.)

Given the animal and human data already available, EPA considers it quite improbable that the new study will detect adverse systemic effects at the lower exposure levels. However, in the event that such effects are observed, EPA will review today's action in light of such data.

EPA wishes to stress that its decision that there is no need to wait for submission of the new inhalation study is based on the Agency's conclusion that the present data are already adequate to support the requisite statutory determination. EPA does not agree with the argument made by AlliedSignal in its comments that previous EPA delisting actions under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) provide precedent that would enable EPA to proceed with delisting under Clean Air Act Section 112 when research which is clearly material to its risk assessment is still underway. Unlike Clean Air Act Section 112(b)(3)(C), which requires EPA to determine that

currently available data are adequate to support a determination that a substance may not reasonably be expected to cause adverse effects, EPCRA Section 313(d)(3) provides that a chemical may be deleted if there is not sufficient evidence to establish that it causes certain adverse effects.

C. Human Effects Information

In comments submitted by PURE and statements by individual citizens at the public hearing, many commenters asserted their belief that there is a relation between various adverse human health effects and caprolactam emissions by the AlliedSignal Irmo facility. The effects described include headaches, allergies, sinus problems, respiratory disorders, multiple chemical sensitivity, chronic fatigue syndrome, various digestive disorders, neurologic disorders, and several types of cancer. Although reports of irritation of the upper respiratory tract are qualitatively similar to the effects observed at far higher concentrations in occupational studies, EPA is not aware of any evidence which would indicate a relation between the occurrence of these common disorders in the general population and caprolactam exposure. EPA is also unaware of any evidence which would support the claimed relationship between caprolactam exposure and the other specific diseases which were mentioned. In the absence of any reliable epidemiologic or clinical information, or any other collateral evidence which would suggest the biological plausibility of the described effects, EPA cannot justify affording any weight to such anecdotal evidence in its risk assessment.

The purported relationship between caprolactam exposure and the symptoms of multiple chemical sensitivity (MCS) requires separate discussion. There is at present no medical consensus concerning the definition or the nature of this disorder. EPA is aware that some individuals and their physicians report they are unusually sensitive to multiple chemicals to which the general population is commonly exposed without ill effect. One person who spoke at the public hearing asserted that she is so sensitive to chemicals that she cannot use a dishwashing machine in her home. While EPA recognizes the formidable challenges and problems which may be faced by such individuals as they attempt to function in modern industrial society, such unusual and extreme sensitivity is not among the effects that EPA was directed to consider in identifying and listing hazardous air pollutants.

EPA is aware that a number of individuals in the Irmo-St. Andrews area have firmly concluded that caprolactam is the cause of health problems which they or their families have

experienced. EPA accepts the concern and personal sincerity of these individuals' beliefs, but is not aware of any scientific evidence which would support them. EPA acknowledges the disappointment its decision to delist will cause these individuals, but respectfully suggests that the substantive changes at the Irmo facility have more practical significance to them than the plausibility of the claimed effects. EPA has taken steps which assure that there will be Federally enforceable reductions of caprolactam emissions at the Irmo facility equivalent to those which would have been required had caprolactam remained on the list of hazardous air pollutants, and that such reductions will be in place years before they would otherwise have been required.

The Agency for Toxic Substances and Disease Registry (ATSDR) commented on the EPA discussion of an ATSDR report in the proposed rule. ATSDR noted that EPA had called the report a ``preliminary screening study,'' although the ATSDR reviewed only the available literature, environmental monitoring data, and written and verbal reports of health concerns from individuals, and no health screening was performed on individuals. ATSDR also noted that the proposed rule had misquoted the ATSDR report, and that its conclusions concerning the Irmo Facility should not be generalized or applied to other facilities.

The use by EPA of the term ``preliminary screening study'' was not intended to imply that any health screening had been performed by ATSDR, and EPA regrets any confusion this phrase may have caused. In its report, ATSDR did reach conclusions regarding the Irmo facility which are consistent with the EPA analysis, but the determination by EPA that the

statutory criterion for delisting has been met is not predicated on the ATSDR conclusions. As far as the quotation from the ATSDR report in the proposed rule, the omission of several words was inadvertent. The correct quotation is:

``* * * the concentration of hazardous substances found in ambient air sampling were not of health concern and the community health concerns were not plausibly related to the release of hazardous substances.'' (correction italicized)

Finally, although the determination by EPA that caprolactam meets the statutory criterion for delisting is generic in nature, EPA never intended to generalize the ATSDR findings to other facilities or the communities in which they are located.

One frequent comment by the residents in the Irmo-St. Andrews area was that EPA should study the residents of that area before proceeding to delist caprolactam. EPA has carefully evaluated the feasibility and scientific value of an epidemiologic study and has determined that it would neither be practical or informative. In its evaluation, EPA utilized five criteria for determining the feasibility of community environmental studies suggested by Bender, et al., in a 1990 article in the American Journal of Epidemiology. A memorandum summarizing this EPA evaluation has been included in the docket.

The EPA evaluation makes it clear that a meaningful study of persons exposed to caprolactam emissions from the Irmo facility cannot be conducted. Key problems with such a study include the selection of biologically plausible health effects in the exposed population, the identification and measurement of other factors which might contribute to these health effects, and the lack of adequate statistical power to detect differences between exposed and unexposed populations.

As noted above, it is difficult to identify the specific health effects which would be the focus of such a study. If there were an unusual cluster of a single rare disease in the community, a credible allegation of a potential relation between that disease and caprolactam exposure, and all persons with that disease from an identified population including exposed individuals could be examined, a case-control study might be practicable. However, none of these factors are present here.

A cohort study of an exposed population (such as students at a nearby elementary school) would also be impractical. The non-specific complaints in the upper respiratory tract which are most frequently asserted by residents to be potentially related to caprolactam exposure have a very high incidence in any population. Such upper respiratory complaints can be caused by other pollutants, allergens, and infectious agents, and it would be difficult if not impossible to adequately control for these confounding factors in the study and control populations. Finally, the size of any potentially exposed valid study population that could be identified would probably not be large enough to provide sufficient statistical power to detect significant differences even if they do exist.

EPA realizes that there is a perception by many concerned citizens that any hypothetical relation between actual exposures and actual health effects can be scientifically studied. Unfortunately, this is not the case. Given the currently available information and the analytic tools provided by current science, EPA sees little or no utility to

an epidemiologic study of caprolactam exposure in the Irmo-St. Andrews area. This is similar to the conclusion reached by ATSDR in its report.

D. Exposure Information

One commenter stated that the exposure estimates by the petitioners and by EPA were incomplete because they did not consider caprolactam emissions from hot mix asphalt (HMA) plants. The commenter estimated that caprolactam emissions from individual HMA plants could exceed the major source threshold of 10 tons per year, and that total caprolactam emissions from such facilities could be as high as 18,000 tons per year. Caprolactam is an ingredient in liquid anti-stripping agents containing bis(hexamethylene)triamine (BHMT), which are used in some HMA plants.

Prior to submission of this comment, EPA was unaware of HMA plants as a potential source of caprolactam emissions. If the commenter's estimates of emissions from HMA plants were determined to be correct, it was clear that the failure of the petitioners to address such emissions in their petition had been a significant omission.

AlliedSignal investigated emissions of caprolactam from HMA plants and submitted comments summarizing its findings. Although the commenter had estimated based on a material safety data sheet for one anti- stripping agent that caprolactam levels in such products are 5%, the actual level of caprolactam found in this product by AlliedSignal was .38%. In nine such products tested by AlliedSignal, the average caprolactam level was .79%, and the highest level found was 1.8%. Based on other assumptions suggested by the original commenter, AlliedSignal estimated that worst-case emissions from an HMA plant using a liquid anti-stripping agent containing the maximum caprolactam level of 1.8% would be 3.6 tons per year. AlliedSignal noted that not all HMA plants use liquid anti-stripping agents, and not all such agents contain BHMT (and thus caprolactam). Based on estimates of the total quantity of liquid anti-stripping agents produced annually, and the percentage of such agents containing BHMT, AlliedSignal concluded that no more than 27 tons/year of caprolactam is emitted from all HMA plants.

EPA considers the estimates by AlliedSignal of caprolactam emissions by HMA plants to be reasonable based on the information provided. Based on these estimates, no single HMA plant would constitute a major source of caprolactam. Because the estimated emissions from plants in the HMA source category are lower than reported emissions from the other source categories evaluated in the original petition, EPA

does not believe that emissions from such sources would affect its conclusion that the statutory criterion for delisting has been met.

Several commenters expressed doubt as to the reliability of the exposure modeling on which the caprolactam delisting petition and the EPA risk assessment are based. In general, EPA believes that the exposure models utilized by the petitioners produce conservative results. Although actual ambient monitoring data around facilities emitting caprolactam is very limited, AlliedSignal submitted information indicating that actual measurements of ambient caprolactam levels at a monitoring station near its Irmo facility operated by the State of South Carolina Department of Health and Environmental Control were generally less than the concentrations for that location which were predicted by modeling.

Several commenters expressed concern that the EPA conclusions regarding the adverse effects of current caprolactam emissions do not assure that new sources with greater caprolactam emissions than those identified in the petition will not emerge in the future. A related concern was that the agreements with AlliedSignal regarding control of caprolactam emissions at its manufacturing facilities will not affect emissions at future facilities.

EPA does not interpret Section 112(b)(3)(C) to require consideration of hypothetical emissions from facilities that might be constructed in the future.

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The logical consequence of such an expansive construction would be that no substance could ever be delisted, due to the hypothetical possibility of some future facility with emissions large enough to cause adverse effects. In the event that some future facility has uncontrolled caprolactam emissions great enough to change the conclusions of the present EPA risk assessment, EPA can revisit its decision to delist caprolactam at that time.

EPA readily acknowledges that the agreements with AlliedSignal do not apply to other caprolactam emitting facilities, either those presently in existence or those which might be constructed in the future. Although EPA has been unable to establish any link between caprolactam emissions at the Irmo facility and health effects in that community, EPA negotiated an agreement with AlliedSignal concerning installation of additional emission controls in order to alleviate the stated concerns of the residents in that community. EPA also reached agreement with AlliedSignal

concerning control of emissions at its Chesterfield, VA manufacturing facility because that facility had large uncontrolled caprolactam emissions analogous to those at the Irmo facility. While EPA does not consider the Federally enforceable reductions in caprolactam emissions at either of these facilities to be essential to meet the statutory criteria for delisting, these reductions do provide substantial additional assurance that adverse human health effects will not occur. Moreover, the agreed reductions will be in place well before any mandatory emission reductions which would have resulted from the continued listing of caprolactam as a hazardous air pollutant.

E. Emission Reductions by AlliedSignal

Several commenters from the Irmo-St. Andrews area expressed doubt concerning the enforceability of the caprolactam reductions at the Irmo facility which have been agreed to by AlliedSignal. Such comments are simply erroneous. AlliedSignal has unequivocally agreed that the key terms and conditions which assure such reductions will be incorporated into the Federally enforceable Title V operating permit for the Irmo facility. This is the same permit which would have been utilized to enforce any emission standard controlling caprolactam emissions from this facility adopted pursuant to Clean Air Act Section 112.

In its comments, PURE argued that EPA should not presume that the emission reductions to be achieved by AlliedSignal at the Irmo facility are equivalent to the reductions which would be required by a Maximum Achievable Control Technology (MACT) standard issued under Section 112, because EPA has not gone through the steps which would be necessary to determine what MACT would be. Since any MACT standard issued for the source category including the AlliedSignal Irmo facility would not be issued until years from now, EPA cannot say with precision what such a standard would ultimately require. However, EPA has determined that the emissions control technology being installed at the AlliedSignal Irmo and Chesterfield facilities is likely to perform at least as well as that which has been demonstrated at other well-controlled facilities.

EPA bases its conclusions concerning the effectiveness of emission controls being installed at the AlliedSignal facilities on the emission and production information contained in the petition and produced by the petitioners during the rulemaking, and on visits by EPA to several operating Nylon 6 production facilities, including the AlliedSignal Irmo facility and the BASF Clemson facility.

(PURE representatives have cited BASF as a company which does a good job of controlling its caprolactam emissions.) EPA has evaluated each of six Nylon 6 production facilities to determine the ratio of the amount of caprolactam emitted to the amount of Nylon 6 fiber production. The ratio of emissions to production at the AlliedSignal Irmo and Chesterfield facilities after all required controls have been installed will be less than the present ratio of emissions to production at all other facilities except the BASF Anderson plant, which has lower emissions because it spins Nylon 6 fiber but receives polymerized caprolactam from another site. Although the analysis underlying a MACT standard would be more detailed, and would likely involve separate analysis of caprolactam emissions for polymerization, depolymerization, and spinning operations, EPA considers it improbable that a MACT standard based on presently demonstrated technologies would require greater control of caprolactam emissions at the AlliedSignal facilities than is required by the agreements AlliedSignal has executed.

Several commenters complained that the agreement between EPA and AlliedSignal does not adequately regulate emergency releases from the plant. Under general MACT provisions, releases during periods of upset and abnormal operation are not considered in determining compliance with MACT standards. Thus, the implicit assumption that a MACT standard would regulate emergency releases more stringently than the agreement is mistaken. In addition, the commenters appear to overestimate the significance of such releases. Figures provided by AlliedSignal indicate that additional caprolactam emissions associated with scheduled maintenance and unscheduled malfunctions of emission control equipment at the Irmo facility represent less than one percent of the total caprolactam emissions by that facility.

The agreement concerning the AlliedSignal Irmo facility does contain provisions which require expeditious reporting of any emission control equipment upset or malfunction, as well as any emergency releases, to the South Carolina Department of Health and Environmental Control. The agreement also requires prompt repair of any malfunctioning emission control equipment, and installation of pressure control devices on those emission points most susceptible to emergency releases.

F. Delisting Criteria

In its comments, PURE asserted that EPA is required to consider occupational exposures in deciding whether to delist caprolactam. EPA firmly disagrees with this comment. The

language of Section 112(b)(3)(C) refers to ``emissions, ambient concentrations, bioaccumulation, or deposition of the substance.'' Nothing in this language suggests that EPA should consider worker exposures in its delisting assessment. Moreover, it would be illogical to assume that worker exposures should be considered in deciding whether to delist when continued listing would not itself lead to any requirement that occupational exposures be controlled.

In its comments, PURE also argued that the proposed delisting would be unlawful because it assumes future compliance by AlliedSignal with the agreed emission reductions, thereby circumventing the purposes of the Clean Air Act. It could be argued that consideration of future emission reductions in a decision to delist a substance from the list of hazardous air pollutants is a reasonable construction of Section 112(b)(3)(C) consistent with the purposes of the Clean Air Act, so long as such reductions will be as enforceable as those which might be required by a MACT standard and will be in place before any MACT standard could be issued. However, in this instance it was not necessary to resolve this question. EPA has determined that

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the petitioners have satisfied the statutory criterion for delisting in Section 112(b)(3)(C) based on the emissions reported in the delisting petition. The agreements by AlliedSignal requiring enforceable reductions in caprolactam emissions at its facilities provide additional assurance that the agency's determination is correct, but are not an essential element in the risk assessment on which that determination is based.

III. Final Rule

A. Rationale for Action

The detailed factual rationale supporting the Agency's initial determination that the criterion in Clean Air Act Section 112(b)(3)(C) had been met is set forth in the proposed rule published in the Federal Register on September 18, 1995 (60 FR 48081). As is apparent from the discussion above, although EPA has done substantial additional analysis pursuant to the comments submitted during the subsequent rulemaking, none of those comments have caused EPA to revise the basic scientific analysis on which that initial determination was predicated. EPA hereby incorporates in its rationale for this final rule the substantive assessment of

potential hazards, projected exposures, human risk, and environmental effects set forth in the proposed rule to delist caprolactam. Based on that assessment, the Agency's evaluation of the comments and additional information submitted during the rulemaking (as summarized above), and on the other materials which have been incorporated in the public docket for this rulemaking, EPA has made a determination that there is adequate data on the health and environmental effects of caprolactam to determine that emissions, ambient concentrations, bioaccumulation or deposition of caprolactam may not reasonably be anticipated to cause any adverse effects to human health or adverse environmental effects. On that basis, caprolactam is hereby deleted from the list of hazardous air pollutants set forth in Clean Air Act Section 112(b)(1). This deletion shall be final on the effective date of this rule.

B. Implementation

Although EPA intends in the future to conduct a rulemaking to codify the hazardous air pollutant list set forth in Clean Air Act Section 112(b)(1) and to correct various technical errors in the statutory list which have been identified since 1990, the list is at present uncodified. Therefore, today's rule does not revise the text of any existing provision of the Code of Federal Regulations. However, on the effective date of this rule, caprolactam will be deleted for all purposes from the list set forth in Section 112(b)(1). To avoid confusion concerning the status of caprolactam, pending the rulemaking which will codify and correct the list set forth in Section 112(b)(1), EPA will add to the Code of Federal Regulations a brief provision confirming that caprolactam has been deleted from the list.

EPA included in the proposed rule to delist caprolactam a provision providing immediate relief, on an interim basis, for certain facilities which might otherwise have been required to apply for Title V operating permits based solely on the continued inclusion of caprolactam on the list of hazardous air pollutants. That provision suspended the listing of caprolactam, for the duration of this rulemaking, solely for the limited purpose of determining the applicability of Title V permitting requirements. The interim relief provided in the proposed rule is no longer necessary and will expire by its own terms on the effective date of this final rule.

C. Effective Date

This final rule will be effective on June 18, 1996, the

date it is published in the Federal Register. Although Section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), provides that substantive rules must be published at least 30 days prior to their effective date, this requirement does not apply to this rule. First, this rule was promulgated pursuant to Clean Air Act Section 307(d), and that provision expressly states that the provisions of Section 553 do not apply to this action. Second, even under Section 553, the requirement that a rule be published 30 days prior to its effective date does not apply to a rule

``which grants or recognizes an exemption or relieves a restriction.''

D. Judicial Review

This final rule deleting caprolactam from the list of hazardous air pollutants in Clean Air Act Section 112(b)(1) is based on a determination of nationwide scope and effect. A petition for judicial review of this final rule may be filed solely in the United States Court of Appeals for the District of Columbia. Any such petition for judicial review of this rule must be filed no later than August 19, 1996. In any resulting action, no objection can be made which was not raised with reasonable specificity during the period for public comment (including the public hearing).

IV. Miscellaneous

A. Executive Order 12866

Under Executive Order 12866 (58 FR 57735, October 4, 1993), EPA must determine whether this rule is ``significant'' and therefore subject to review by the Office of Management and Budget under the Executive Order. The Order defines ``significant regulatory action'' as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal

mandates, the President's priorities, or the principles set forth in the Executive Order.

This action will not result in an annual effect on the economy of $100 million or another adverse economic impact, does not create a serious inconsistency or interfere with another agency's action, and does not materially alter the budgetary impacts of entitlement, grants, user fees, etc. While States may lose Title 5 permit fees as a direct result of this rule, the number of affected facilities is not believed to be significant. However, since this action is the Agency's first decision to modify the hazardous air pollutant list, EPA believes that it could be construed as raising novel legal or policy issues and has therefore submitted this rule for OMB review under Executive Order 12866.

B. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. This rule will reduce regulatory burdens on small businesses which would otherwise be associated with retention of caprolactam on the list of hazardous air pollutants. EPA has determined that this rule will have no adverse effect on small businesses. Accordingly, this rule will not have ``a significant impact on a substantial number of small entities,'' as that phrase is utilized in Section 605(b) of the Regulatory Flexibility Act, as amended.

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C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995, EPA must prepare a written statement to accompany any rules that have ``Federal mandates'' that may result in the expenditure by the private sector of $100 million or more in any one year. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objective of such a rule and that is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising small governments that may be significantly and uniquely affected by the rule.

The Unfunded Mandates Act defines a ``Federal private sector mandate'' for regulatory purposes as one that, among other things, ``would impose an enforceable duty upon the private sector.'' This final rule to modify the hazardous air pollutant list to delete caprolactam is deregulatory in nature and does not impose any enforceable duties upon the

private sector. Therefore, this rulemaking is not a ``Federal private sector mandat'' and is not subject to the requirements of Section 202 or Section 205 of the Unfunded Mandates Act. As to Section 203, EPA finds that small governments will not be significantly and uniquely affected by this rulemaking.

D. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) of the Administrative Procedures Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ``major rule'' as defined by section 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances.

Dated: June 7, 1996.
Carol M. Browner,
Administrator.

40 CFR part 63 is amended 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.

Subpart C--[Amended]

2. Subpart C is amended by adding Sec. 63.60 and adding and reserving Secs. 63.61 through 63.69 to read as follows:

Sec. 63.60 Deletion of caprolactam from the list of hazardous air pollutants.

The substance caprolactam (CAS number 105602) is deleted

from the list of hazardous air pollutants established by 42 U.S.C. 7412(b)(1).

Secs. 63.61-63.69 [Reserved]

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