TO: Distribution

~~TGG: JGL~~: ~~FGJ~~: ~~AC~~: AJO: RF

XF: None

FROM: T. G. Grumbles
DATE: September 24, 1991

Interoffice Communication

VISTA

SUBJ: JOHN GRAY INSTITUTE STUDY ON CONTRACT LABOR IN THE PETROCHEMICAL INDUSTRY

Attached is a copy of the subject study. It is offered without comment as I haven't "digested" the report yet. An executive summary can be found beginning on Page xiii.

T. G. Grumbles

dlj
.329

Attachment

cc: THH, RDG

SAFETY DIRECTORS

Bruce Trego-Aber, Brent White-Balt, George Williams-Blane, Matt Tonkovich-Hmd, K. L. Fogg-LCCP, R. V. Gantz-LCLAB, Mike Lunsford-LCVCM, Chris Markerson-Okc, Greg Lipps-Premiere, R. B. Martin-Austin, J. R. Drumwright, J. G. Farrier

VVV 000007838

Vista Chemical Company

900 Threadneedle
Houston, Texas 77079-2990
(713) 588-3000

P.O. Box 19029
Houston, Texas 77224-9029
Fax (713) 588-3236

TGG: JCL: EGJ: AC: AJO: RF

XF: none

VISTA

September 24, 1991

Robert Sheriff, CIH
Atlantic Environmental, Inc.
2 East Blackwell Street, Suite 24
Dover, NJ 07801

Dear Bob:

Attached is recent correspondence from EPA regarding the agency's intention to begin an effort under TSCA Section 5(e) to develop exposure limits and sampling methods for new chemicals.

It would seem this is an issue that the Emerging Issues Committee should look into. I'm not sure we need another agency writing health regulations.

Sincerely,

Thomas G. Grumbles, C.I.H.
Manager Environmental Affairs

dlj

cc: Loren Anderson-PPG, Dave Penney-Austin

Attachment

cc Dave Penney

CHEMICAL MANUFACTURERS ASSOCIATION

Fed. Exp.
September 13, 1991

TO: Industrial Hygiene Issues Task Group

SUBJECT: New Chemical Exposure Limits

Enclosed is EPA's draft generic TSCA 5(e) Order containing New Chemical Exposure Limits (NCELs) provisions. CMA has an opportunity to comment on this document. CMA's Chemical Reporting Task Group (CRTG) has obtained an extension for comments to October 18, 1991.

Please review the document and provide your comments in writing directly to Diane Layne, CRTG staff executive. You can reach her by phone at 202/887-1365, if you have any questions on this document or the CRTG's comment plans. CMA's fax number is 202/887-1237.

The following tentative schedule will be followed to complete CMA's comments to EPA:

1. Comments to Diane Layne by September 20, 1991
2. Compiled comments to CRTG and IHITG for review by September 24 or 25, 1991 (a quick turnaround time will be given)
3. Submit comments to the Health and Safety Committee for approval at October 16, 1991, meeting
4. Submit comments to EPA by October 18, 1991

Thank you in advance for your assistance.

Sincerely,

Karen W. Creedon

Karen W. Creedon
Manager
Health Programs

cc w/o attachments: E. Currie, D. Layne, E. Winkelman, E. Gormley, E. Patterson, K. Kunzer, S. Tirey

VVV 000007840

2501 M Street, NW, Washington, DC 20037 202-887-1100 Panafax 202-887-1237 Telex 89617 (CMA WSH)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 6, 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Geraldine V. Cox, Ph.D.
Vice President - Technical Director
Chemical Manufacturers Association
2501 M Street, NW
Washington, DC 20037

Re: TSCA §5(e) New Chemical Exposure Limits

Dear Ms. Cox:

Introduction

I am writing to enlist your assistance in a very important new initiative being undertaken within the New Chemicals Program (NCP) at the Environmental Protection Agency (EPA). The NCP is exploring new techniques for controlling workplace inhalation exposures to those new chemicals that EPA decides warrant regulation under section 5 of the Toxic Substances Control Act (TSCA). I would like you to take time to review the enclosed document and provide any comments you might have.

Enclosed is a copy of a newly-developed generic TSCA section 5(e) Order containing (starting at page 14) "New Chemical Exposure Limits" (NCELs) language. Orders issued under section 5(e) that contain these NCELs provisions are intended to prevent potential unreasonable risks to workers via inhalation exposures to new chemical substances described in premanufacture notices (PMNs) submitted pursuant to section 5(a)(1) of TSCA. Comparable NCELs provisions will soon be incorporated into "significant new use rules" (SNURs) promulgated at 40 CFR Part 721 under section 5(a)(2) of TSCA.

VVV 000007841

Background

Section 5 of TSCA authorizes EPA's "New Chemicals Program." Section 5(a)(1) of TSCA requires submission of written notice to EPA at least 90 days before commencement of commercial manufacture or import of a "**new** chemical substance" and before manufacture or processing of **any** chemical substance for an activity which EPA determines, by rule, constitutes a "significant new use" due to potentially increased exposures. Upon review of a premanufacture notice ("PMN") or significant new use notice ("SNUN"), EPA may

determine that there is insufficient information to evaluate the human health and environmental effects of the substance and that the substance may present an unreasonable risk of injury to health or the environment. Upon making such a determination, EPA may issue an Order under section 5(e) of TSCA to "prohibit or limit" activities associated with the substance. As a matter of policy, whenever EPA issues a section 5(e) Order for a new chemical substance, EPA also promulgates a significant new use rule ("SNUR") under section 5(a)(2) that requires other manufacturers and processors of the same new chemical substance to notify EPA if they intend to pursue activities at variance with the section 5(e) Order requirements.

Section 5 of TSCA gives EPA broad authority to regulate possible risks from new chemical substances. This program was specifically designed by Congress to regulate risks presented by new chemicals before they enter commerce. TSCA does not require manufacturers of new chemical substances to test their substances for human health or environmental effects prior to submission of a PMN. Therefore, EPA has been given very broad authority under §5 of TSCA to regulate a new chemical substance when the available information regarding possible adverse effects of the substance is insufficient and the Agency finds that (in the absence of data) the substance "may present" unreasonable risk. Moreover, the authority in section 5(e) to "prohibit or limit" activities associated with a new chemical substance which may present unreasonable risk gives EPA broad discretion as to how to regulate to control such activities. Typically, in the face of concerns about a new chemical substance, EPA and the substance's manufacturer will negotiate an agreement under §5(e) of TSCA which requires the submitter to initiate actions to limit exposure or release of the substance to mitigate risk pending the development of the data necessary for a more thorough evaluation.

Control of Inhalation Risk in the TSCA §5 New Chemicals Program

To date, EPA's New Chemicals Program has issued Consent Orders under §5(e) of TSCA on approximately 600 chemical substances to control potential unreasonable risks to human health or the environment. In many cases, this has included negotiated agreements designed to control potential inhalation risks to workers by the use of workplace controls including specific respirators selected by EPA based on its limited data and reasonable worst-case estimates of toxicity and inhalation exposure. These new substances subject to EPA action have not been subject to action by other federal authorities such as the Occupational Safety and Health Administration due to their status as chemicals which have not yet entered commerce. In the absence of toxicity data on the PMN substance itself, estimates of toxicity are frequently based on test data on chemicals with molecular structures similar to the PMN substance. EPA's selection of what respirator to require is based on estimates regarding workplace

airborne concentrations, the predicted potency of the PMN substance, the physical form of the new chemical substance, the respirator's National Institute for Occupational Safety and Health (NIOSH) Assigned Protection Factor, and the professional judgment of EPA's industrial hygienists.

EPA's Desire to Move Toward New Chemical Exposure Limits

Without actual toxicity data on the PMN substance and without actual measurement of the workplace airborne concentration of the substance, the specific respirator required by EPA may be overprotective or, conceivably, underprotective. Furthermore, respirators can be: (1) uncomfortable and therefore not worn by workers, (2) cumbersome and therefore detrimental to other physical aspects of workplace safety, (3) inappropriate for the combination of chemicals and other conditions that actually exist in the workplace, and (4) not cost-effective. Therefore, OTS is interested in moving toward more performance-based requirements that encourage pollution prevention and source reduction to mitigate inhalation exposures in the workplace.

To meet this objective, OTS intends to negotiate chemical-specific performance-based exposure limits for workplace airborne concentrations of specific PMN substances reported by their manufacturer. The use of "New Chemical Exposure Limits" (NCELs) would be limited to new chemicals that are subject to PMN reporting and that are not otherwise regulated by EPA or other federal agencies. The NCELs provisions are modeled after the permissible exposure limits (PELs) promulgated by the Occupational Safety and Health Administration (OSHA) at 29 CFR Part 1910 pursuant to sections 6(a) and 6(b) of the Occupational Safety and Health Act. When included in a section 5(e) Order or SNUR, the NCELs provisions allow a company the alternative of using engineering controls and work practices to maintain a specified workplace airborne concentration that is set by EPA and that the company must verify by performing actual monitoring. As noted in the enclosed NCELs §5(e) Order language, NCELs are "interim levels determined by EPA based on the limited information available to the Agency at the time of development of this Order." If, subsequently, more data on a PMN substance are developed or another federal agency (such as OSHA) regulates workplace exposures, EPA could revoke or modify the NCEL.

Summary

Enclosed is a copy of a newly-developed generic TSCA section 5(e) Order containing (starting at page 14) "New Chemical Exposure Limits" (NCELs) language which may be employed in future TSCA section 5(e) Orders and SNURs. I am interested in receiving your comments on the proposed language by **September 13, 1991.** I am particularly interested in receiving comment on the appropriateness of the analytical requirements in subsection B. of the NCELs

provisions. However, please feel free to comment on any other aspect of this project. (Also enclosed is a NCELs flow chart that provides a simplified illustration but does not substitute for the requirements specified in the NCELs section of a TSCA §5(e) Order.)

Thank you very much for your interest and assistance. Please direct any comments or questions to Roy Seidenstein of my staff. Roy's telephone number is (202) 382-2252 (changing to 260-2252 after August 23).

Sincerely,

Linda Vhen Moos for

John W. Melone, Director
Chemical Control Division

Enclosures

cc: Mark A. Greenwood
Joseph S. Carra
Lawrence E. Culleen
Roy S. Seidenstein

• D R A F T •

TABLE OF CONTENTS

I. INTRODUCTION

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-_____ submitted by _____ ("the Company"), to take effect upon expiration of the PMN review period.

Under §15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of §5 or any order issued under §5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to §16, and to specific enforcement and seizure pursuant to §17.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

( ) submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a total of _____ kilograms of the PMN substance;

( ) provide its workers personal protective equipment to prevent dermal exposure;

( ) provide its workers respirators to prevent inhalation exposure;

( ) as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substance at or below a specified New Chemical Exposure Limit ("NCEL") verified by actual monitoring data;

( ) label the PMN substance and provide Material Data Safety Sheets

(MSDS) and worker training in accordance with the provisions of the Hazard Communication Program section;

( ) not manufacture the PMN substance _____

_____;

( ) not process the PMN substance _____

_____;

( ) not use the PMN substance _____

_____;

( ) distribute the PMN substance only to a person who agrees to follow comparable restrictions (except the testing requirements) and to not further distribute the PMN substance until it has been completely reacted;

( ) distribute the PMN substance only _____

_____;

( ) dispose of the PMN substance only by _____;

( ) comply with the Release to Water provisions;

( ) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Chemical Identity:

Specific:

Generic:

Use:

Specific:

Generic:

Maximum 12-Month Production Volume:

Test Data Submitted with PMN:

IV. EPA'S ASSESSMENT OF RISK

Health Effects Summary:

Concerns:

Basis:

Absorption:

New Chemical Exposure Limit: ____ as an 8-hour time-weighted average.

Exposure Summary:

	Manufacture	Process	Use	Consumer
# Sites				
# Persons/site				
# Days/Year				
Amt. Dermal Exp.				
Amt. Inhal. Exp.				
Amt. Drinking Water Exp.				

Environmental Effects Summary:

Environmental Release Summary:

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for_____

_____

from exposure to the PMN substance. EPA therefore concludes, pursuant to §5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the health effects of the PMN substance.

B. In light of the potential risk of_____

_____posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to §5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

C. In light of the estimated production volume of, and human exposure to, the PMN substance, EPA has further concluded, pursuant to §5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and there may be significant or substantial human exposure to the substance.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

The following additional information would be required to evaluate the following effects which may be caused by the PMN substance:

Information	Effects	Guidelines

The Order does not require submission of the above information at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

_____ ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substance _____

_____

_____

("the PMN substance") in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the _____

_____

effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except under the following conditions:

TESTING

(a) Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment, which information is required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order.

(b) The Company shall notify, in writing, the EPA Laboratory Data Integrity Assurance Division, Office of Compliance Monitoring (EN-342), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;

2. The name and address of the laboratory which will conduct the study; and

3. The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

4. The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) (e.g., 40 CFR 797 or 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(d) The Company is prohibited from manufacturing or importing the PMN substance beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section:

Production Limit	Study	Guideline

(e) The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA

no later than 14 weeks prior to exceeding the applicable production limit. The report shall be submitted to EPA in accordance with the standards for the reporting of study results in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, with regard to those subparagraphs, the word "shall" will be used in place of the word "should" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgement, that an adequate evaluation of the study cannot take place in the absence of these items. When the tests required pursuant to the terms of this Order do not contain test guidelines in Parts 797 and 798 above, EPA shall, in writing to the Company, describe the type of data required to adequately evaluate the test data.

(f) The Company is not required to conduct a study specified in paragraph (d) of this Testing Section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by

reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h)(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA

in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i)(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and

(e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j)(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in

subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part III. of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) During manufacturing, processing, and use of the PMN substance at any site controlled by the Company, the Company must establish a program whereby:

(1) Each person who is reasonably likely to be dermally

exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in a form listed in subparagraph (a)(6) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 29 CFR 1910.133.

(2) In addition to the personal protective equipment described in subparagraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs and torso. Clothing provided under this subparagraph (a)(2)(iv) need not be tested or evaluated under the requirements of subparagraph (a)(3).

(3) The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to

establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-89 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(6) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-approved respirator from one of the categories listed in subparagraph (a)(5) of this

section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR Part 11.

(5) The following NIOSH-approved respirators meet the minimum requirements for subparagraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous mode and equipped with a hood or helmet or tight-fitting facepiece.

(iv) Category 21C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters.

(v) Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.

(vi) Category 21C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

(vii) Category 21C air-purifying respirator equipped with a high efficiency particulate filter including disposable respirators.

(viii) Category 23C air-purifying respirator equipped with a full facepiece and combination cartridges approved for

paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(ix) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(x) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xi) Category 23 powered air-purifying respirator equipped with combination cartridges approved for paints, lacquers, and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xii) Category 23C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges.

(xiii) Category 23C air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges.

(xiv) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and organic gas/vapor cartridges.

(xv) Category 23C air-purifying respirator equipped with organic gas/vapor cartridges, including disposable respirators.

(6) The following forms of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Fume.

(iv) Smoke.

(v) Vapor.

(vi) Gas.

(b) If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this protection in the workplace section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of the Hazard Communication Program section of this Order identifies cancer as a potential human health hazard of the PMN substance. This exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

NEW CHEMICAL EXPOSURE LIMITS

A. ALTERNATIVE TO REQUIREMENTS OF RESPIRATOR SECTION

EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable. Whenever a person is reasonably likely to be exposed to the PMN substance by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limits section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(1) submit to EPA, and receive EPA's written approval of, a copy of the Company's proposed sampling and analytical method in accordance with subsection B. of this New Chemical Exposure Limits section;

(2) obtain monitoring results in accordance with this New Chemical Exposure Limits section; and

(3) based on those monitoring results, select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substance by inhalation use the appropriate respiratory protection specified in paragraph D.(2) of this New Chemical Exposure Limits section.

B. APPROVAL OF SAMPLING AND ANALYTICAL METHOD

(1) Delegation of Approval Authority. The authority to render the written approval described in this subsection B. is hereby delegated to the Chief of the New Chemicals Branch (or a higher ranking official).

(2) Applicability. The requirements of this subsection B. (except paragraph (3) "contents of submission" and where indicated otherwise) apply to both (i) the initial submission and approval of the sampling and analytical method and (ii) subsequent monitoring conducted pursuant to the terms of this New Chemical Exposure Limits section. Any deviation from the requirements of this subsection B. must be approved in writing by EPA.

(3) Contents of Submission. Before initially commencing monitoring, the Company shall submit to EPA, and receive EPA's written approval of, a copy of the sampling and analytical method, including the information described in sections 2.1, 2.3, and chapters 3.0, 4.0, and 5.0 of the September 9, 1987 "OTS Guidance Document for the Preparation of Quality Assurance Project Plans." (However, development of a complete Quality Assurance Project Plan as described therein is not required.) The submission shall also include a detailed description of the PMN substance to be measured (including properties of the PMN substance pertinent to its measurement), detailed written justification for the sampling and analytical methodology and instrumentation selected, and any reports on previous monitoring conducted for the chemical, both in published literature and by the Company. The submission shall also

include validation results evidencing that the sampling and analytical method satisfies the quantitative and qualitative (e.g., chromatographic peak identification criteria) measures of performance required by this subsection B. The validation results submitted shall include but not be limited to any field sampling data, sample volumes, instrument standard calibration curves used, standard raw data, and sample raw data, including chromatograms, spectrograms, etc. Quality control sample data shall also be reported and summarized in tabular form.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) NCEL quantitation limit (NQL). The NQL must be one order of magnitude below the NCEL. At the NQL, the PMN substance must be reliably quantified to meet the accuracy and precision requirements as defined in subsection B. The analytical method must be capable of quantifying the PMN substance from the NQL through 2000 times the NCEL.

(ii) detection limit signal to noise ratio. The detection limit of the analytical procedure is defined as the amount of PMN substance that can produce a signal response approximately five times greater than the baseline noise. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The detection limit for

the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iii) instrument calibration. During each week of both method development and subsequent monitoring, the Company shall conduct both an initial instrument calibration and a continuing calibration. The initial calibration shall be based on a minimum of five calibration standards with the lowest concentration at the NQL. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples taken. If the continuing calibration sample does not fall within ± 25% of the initial calibration value, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be reanalyzed.

(iv) calculated percent recovery. Recovery must be determined by either taking a sample containing a known quantity of the PMN substance from a controlled environment (e.g., a sealed chamber) or by injecting a known concentration of the PMN substance onto the sample collection device (known as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or equal to 70% and less than or equal to 120%. During method development, a minimum series of seven matrix spikes must be analyzed. Two of the seven spikes must be at a concentration 0.5 times the NCEL, three at the NCEL concentration, and two at twice the NCEL concentration. During subsequent monitoring, at least 1 matrix spike per every ten monitoring

samples shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.) Verification of the spike concentrations for the PMN substance must be included in the sampling and analytical method submission to EPA.

(v) sampling device capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the PMN substance without loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use absorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration two times the NCEL and at a relative humidity of 80% in the dilution air stream. Breakthrough is defined to have occurred when the effluent from the sampling device contains a concentration of the PMN substance equal to five percent (5%) of the upstream concentration. (A written description of how breakthrough testing was performed must be provided.)

(vi) desorption efficiency and sample storage study. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the chemical substances at the NCEL concentration must be prepared. An average recovery of at least 75% must be obtained for the six samples. A sample storage evaluation must also be performed. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection

or extraction (if applicable) to analysis and storage conditions must be specified and data provided to justify the stated time periods.

(5) Precision. The sampling and analytical method must clearly demonstrate the following:

(i) relative percent difference. The Company must demonstrate that the relative percent difference ("RPD") between duplicate samples is less than or equal to 40% on the average, with no single set of duplicate samples greater than 50% RPD. Duplicate samples are defined to be two samples taken under the same conditions at the same time. Relative percent difference is defined as the absolute value of the difference between a pair of duplicate samples divided by the mean value of the samples. During method development, relative percent difference must be determined from duplicate collection devices and be based on the analysis of no less than three pairs of samples at concentration levels of 0.5, 1, and 2 times the NCEL concentration. During subsequent monitoring, the Company shall take at least one duplicate sample, and at least one additional duplicate sample per every 10 samples taken.

(6) Interpretation of Accuracy and Precision Data

(i) If a single matrix spike recovery is less than 70% recovery or greater than 120% or the precision (RPD) data for duplicates is greater than 40% on average or greater than 50% for any single set of duplicate samples, then the Company must reprepare the matrix spike, resample, and reanalyze all samples

associated with such matrix spike or duplicate samples.

(ii) For percent recoveries less than 90% but greater than 70%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value 30 $mg/m^3/(0.75) = 40$ mg/m^3 when determining whether the levels are below the exposure limit. When the performance of matrix spike recoveries fall consistently above 50% and below 70%, the data may be submitted to EPA for special consideration.

(7) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(8) Representativeness. All sample conditions used to develop the methodology shall be representative of the actual workplace environment to be monitored. Conditions such as the presence of other chemicals, lighting, humidity, etc. must be similar to the conditions in the workplace to be monitored.

(9) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the approved sampling and analytical method in such a way that might invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company revalidates the method and confirms that the requirements for precision and accuracy in paragraphs B.(4) and (5) are met. Examples of possible changes

include but are not limited to: introduction of a new chemical substance to the workplace which may interfere with the analysis of the PMN substance; introduction of light to the workplace which may interfere with a light-sensitive PMN substance; or introduction of water/increased humidity to the workplace which could react with the PMN substance and cause difficulties in collection and analysis.

(10) Fibers. For PMN substances in the form of fibers, in addition to submitting the analytical methodology and validation data in accord with previous requirements, the Company must provide a full characterization of the fiber chemical composition and nature (vitreous, crystalline, or variation thereof). The Company must also provide a full characterization of the size ranges of the fiber, both lengths and diameters. The determination of the percentage of fiber sizes (lengths and diameters) present must be performed both on bulk fiber and on air samples collected in the workplace. This characterization must include, at a minimum, a full analysis by transmission electron microscopy to confirm the smallest sizes of fibers present in the product and to report the percentage of fibers in the sample within the various size ranges by length and diameter. If all fiber diameters are greater than 0.25 um, then a detailed explanation of why an alternative microscopy technique is appropriate must be reported. Counting rules for quantifying the number of fibers present in the sample must be reported, as well as fiber identification criteria. If the Company desires to utilize instrumentation capable of measuring

fibers only in the optical microscopy size ranges, a study demonstrating the applicability of the technique to the particular manufacturing process and its variations and the fiber is required. If the manufacturing process changes, the Company must reanalyze the fibrous material to confirm no changes in size ranges or structure have occurred. Changes in the manufacturing method could include but not be limited to alterations in the production process which would change the fiber sizes (in diameter and length) or alter the structure of the fiber (crystalline, vitreous, etc.).

(11) EPA's approval of the sampling and analytical method does not ensure that the methods will produce valid monitoring data. The Company is ultimately responsible for ensuring the validity of their monitoring data.

C. NEW CHEMICAL EXPOSURE LIMITS (NCELs)

The following new chemical exposure limits (NCELs) for the PMN substance are interim levels determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCELs for the PMN substance are as follows:

(1) Time-weighted average (TWA) limit. The Company shall ensure that no person is exposed to an airborne concentration of the PMN substance in excess of _____ as an 8-hour time-weighted average, without using a respirator in accordance with either the Protection in the Workplace section of this Order or subsection D. of this New Chemical Exposure Limits section.

(2) Short-term exposure limit (STEL). The Company shall

ensure that no person is exposed to an airborne concentration of the PMN substance in excess of _____ as averaged over any 15 minute period, without using a respirator in accordance with either the Protection in the Workplace section of this Order or subsection D. of this New Chemical Exposure Limits section.

D. RESPIRATORY PROTECTION

(1) General. Whenever the Company has conducted monitoring in accordance with subsection E. of this New Chemical Exposure Limits section and the last measured airborne concentration of the PMN substance for any person who is reasonably likely to be exposed to the PMN substance by inhalation exceeds a NCEL, the Company shall provide those persons the respirators specified in paragraph D.(2) below, rather than the respirator identified in the Protection in the Workplace section of this Order, and shall ensure that the respirators are used in accordance with 29 CFR 1910.134 and 30 CFR Part 11. When the Company has not actually measured the airborne concentration of the PMN substance in accordance with this New Chemical Exposure Limits section, the Company shall comply with the respirator requirements in the Protection in the Workplace section of this Order.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted monitoring in accordance with subsection E. of this New Chemical Exposure Limits section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substance by inhalation use at least the

respiratory protection which corresponds in the following table to the actually measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than actually measured).

[Note - The following table for particulate exposure is provided here for purposes of illustration. The other tables at the end of this New Chemical Exposure Limits section may be inserted depending on the physical form of the PMN substance.]

PARTICULATE EXPOSURE:

Measured Concentration of PMN Substance	Required Respiratory Protection
≤ NCEL	No respirator required.
≤ (10 x NCEL)	Category 21 C air-purifying respirator equipped with a high efficiency particulate filter, including disposables, or Category 19C Type C supplied-air respirator.
≤ (25 x NCEL)	Category 21 C powered air-purifying respirator equipped with a loose fitting hood or helmet and high efficiency particulate filters. Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a hood or helmet.
≤ (50 x NCEL)	Category 21 C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters. Category 21 C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate

	filters.
	Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a tight-fitting facepiece.
≤ (2000 x NCEL)	Category 19 C Type C supplied-air respirator operated in pressure demand or other positive pressure mode, and equipped with a full facepiece.
> (2000 x NCEL)	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode.
	Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing aparatus operated in a pressure demand or other positive pressure mode.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual monitoring conducted in accordance with subsection E. of this New Chemical Exposure Limits section, before the Company may make any reduction in that respiratory protection, the Company must verify by 2 consecutive measurements taken at least 7 days apart that the new respiratory protection is appropriate in accordance with paragraph D.(2).

E. MONITORING POTENTIAL EXPOSURE

(1) General.

(i) The "action level" means an airborne concentration of the PMN substance of _____ calculated as an 8-hour time-weighted average. (The action level may be exceeded without penalty; its purpose pertains solely to determination of the requisite monitoring frequency.)

(ii) Whenever monitoring is required by this New Chemical Exposure Limits section, the Company shall take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substance would be if respirators were not worn, by sampling the breathing zone air of at least one person that represents and does not underestimate the potential exposure of every person performing the same or substantially similar operations in each work shift in each job classification in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substance is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the EPA-approved sampling and analytical method submitted pursuant to subsection B. of this New Chemical Exposure Limits section. When a value less than the method detection limit is measured, the measured concentration of potential exposure shall be considered to be equal to the value of

the method detection limit.

(iv) Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for each exposure group.

(v) Determinations of compliance with the STEL shall be made from 15 minute breathing zone samples measured at operations where there is reason to believe that the maximum short-term exposures will occur, such as during, but not limited to, the following operations: _____. All monitoring which is conducted at the times specified by this New Chemical Exposure Limits section shall include both a TWA and STEL.

(2) Initial monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial monitoring to accurately determine the airborne concentration of the PMN substance for each exposure group in which persons may be exposed to the PMN substance.

(3) Periodic monitoring. If any representative samples taken during the initial monitoring reveal an airborne concentration at or above the action level, the Company shall repeat the monitoring for that exposure group at least every 6 months. If the PMN substance is not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct monitoring until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than the 6 month

period does not constitute grounds for postponement of the 6 month deadline to conduct monitoring.

(4) Termination of monitoring.

(i) If representative samples taken during the initial monitoring reveal an airborne concentration to be below the action level, the Company may discontinue monitoring for that exposure group, except when additional monitoring is required by paragraph E.(5) of this New Chemical Exposure Limits section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph E.(5) of this New Chemical Exposure Limits section.

(5) Additional monitoring. For a previously monitored exposure group, the Company shall conduct the initial monitoring and any periodic or additional monitoring required by subsection E. of this New Chemical Exposure Limits section within 7 days of any:

(i) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance;

(ii) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substance; and

(iii) whenever else the Company has any reason to

suspect a change that may reasonably result in new or additional exposures to the PMN substance.

(6) Annual report to document need for additional monitoring. If monitoring for a particular exposure group has been terminated pursuant to paragraph E.(4) of this New Chemical Exposure Limits section, then at least every year after the date of last monitoring, the Company shall answer in writing the following questions regarding events which may have occurred since either the last monitoring or the last report required by this paragraph E.(6) in order to document whether monitoring must be resumed pursuant to paragraph E.(5). If the PMN substance is not manufactured, processed, or used at all during a given calendar year, the Company is not required to answer the following questions until manufacture, processing, or use of the PMN substance is resumed. However, cessation of manufacturing, processing and use of the PMN substance for less than one year does not constitute grounds for postponement of the one year deadline to answer the following questions. Any additional monitoring required by paragraph E.(5) shall be conducted before any person is exposed without using at least a respirator of the type required by this Order and shall not be delayed pending the completion of the one year period specified in this paragraph.

(i) Have there been any changes in processes, operations, work tasks, or worker activities which could result in additional or new airborne PMN substance and subsequent inhalation exposure? If so, describe how and when.

(ii) Has the production volume or capacity increased by 20 percent or more during the last 6 months? If so, describe how and when.

(iii) Have there been any other production volume, process, control or handling procedure changes that may reasonably cause new or additional airborne PMN substance and subsequent inhalation exposure? If so, describe how and when.

(iv) Have any actions intended to mitigate exposures to or below the NCELs been implemented?
If so, describe how and when.

(v) Have there been any spills, leaks, ruptures or other breakdowns that may reasonably cause new or additional exposure? If so, describe how, when, and any action taken to mitigate exposure.

(7) Notification of monitoring results.

(i) Within 15 working days after receipt of the results of any monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCELs, the monitoring results, and any corresponding respiratory protection required by paragraph D.(2). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCELs are exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to

or below the NCELs, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

F. RECORDKEEPING

(1) Whenever the Company opts to comply with this New Chemical Exposure Limits section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) Records documenting all monitoring dates, duration, and results of each sample taken;

(ii) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(iii) A description of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section B.;

(iv) Records documenting compliance with the Good Laboratory Practice Standards at 40 CFR Part 792.

(v) The type of respiratory protective devices worn by the monitored person, if any;

(vi) Any conditions that might have affected the monitoring results;

(vii) The report required by paragraph E.(6) to document the need to resume monitoring.

(viii) Notification of monitoring results required by paragraph E.(8).

(ix) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance.

(x) Records documenting any actions taken to mitigate exposures to the PMN substance.

(xi) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure.

PAINT SPRAY MIST EXPOSURE:

Measured Concentration of PMN Substance	Required Respiratory Protection
≤ NCEL	No respirator required.
≤ (10 x NCEL)	Category 23 C air-purifying respirator equipped with combination cartridges approved for paints, lacquers and enamels[2], including disposables, or Category 19C Type C supplied-air respirator.
≤ (25 x NCEL)	Category 23 C powered air-purifying respirator equipped with a loose fitting hood or helmet and combination cartridges approved for paints, lacquers and enamels[2]. Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a hood or helmet.
≤ (50 x NCEL)	Category 23 C air-purifying respirator equipped with a full facepiece and combination cartridges approved for paints, lacquers and enamels[2]. Category 23 C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers and enamels[2]. Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a tight-fitting facepiece.
≤ (2000 x NCEL)	Category 19 C Type C supplied-air respirator operated in pressure demand or other positive pressure mode, and equipped with a full facepiece.
> (2000 x NCEL)	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive

pressure mode.

Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing aparatus operated in a pressure demand or other positive pressure mode.

[2] Approval label may preclude use for some paints, lacquers or enamels.

ORGANIC VAPOR EXPOSURE

The following table shall be used until data on cartridge performance is submitted to, and approved in writing by, EPA.

Measured Concentration of PMN Substance	Required Respiratory Protection
≤ NCEL	No respirator required.
≤ (25 x NCEL)	Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a hood or helmet.
≤ (50 x NCEL)	Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a tight-fitting facepiece.
≤ (2000 x NCEL)	Category 19 C Type C supplied-air respirator operated in pressure demand or other positive pressure mode, and equipped with a full facepiece.
> (2000 x NCEL)	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode. Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing aparatus operated in a pressure demand or other positive pressure mode.

ORGANIC VAPOR EXPOSURE

The following table shall be used only after data on cartridge performance is submitted to, and approved in writing by, EPA.

Measured Concentration of PMN Substance	Required Respiratory Protection
≤ NCEL	No respirator required.
≤ (10 x NCEL)	Category 23 C air-purifying respirator equipped with organic gas/vapor cartridges, including disposables, or Category 19C Type C supplied-air respirator.
≤ (25 x NCEL)	Category 23 C powered air-purifying respirator equipped with a loose fitting hood or helmet and organic gas/vapor cartridges. Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a hood or helmet.
≤ (50 x NCEL)	Category 23 C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges. Category 23 C powered air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges. Category 19 C Type C supplied-air respirator operated in continuous flow mode, and equipped with a tight-fitting facepiece.
≤ (2000 x NCEL)	Category 19 C Type C supplied-air respirator operated in pressure demand or other positive pressure mode, and equipped with a full facepiece.

> (2000 x NCEL)	Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode. Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing aparatus operated in a pressure demand or other positive pressure mode.

HAZARD COMMUNICATION PROGRAM

(a) Written hazard communication program. The Company shall develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list containing the identity of the PMN substance. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of

the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling. (1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process

sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency

procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the

identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to

protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. The Company must ensure

that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substance and whenever the PMN substance is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substance, including

specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low concentrations in mixtures. If the PMN substance is present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of the PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing hazard communication program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health, environmental hazard, exposure, and precautionary statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) skin irritation.

(ii) respiratory complications.

(iii) central nervous system effects.

(iv) internal organ effects.

(v) birth defects.

(vi) reproductive effects.

(vii) cancer.

(viii) immune system effects.

(ix) developmental effects.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) avoid ingestion.

(iv) use respiratory protection.

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(ii) spill clean-up restrictions apply.

(iii) do not release to water.

(5) Each human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substance by any other person.

(2) Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) When EPA promulgates a final SNUR for the PMN substance

and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture the PMN substance:

(1) In non-enclosed processes;

(2) In the United States;

(3) Beyond an aggregate manufacture and importation volume of_____;

(4) Beyond an annual manufacture and importation volume of _____;

(5) In the form of a powder;

(6) In the form of a solid;

(7) In the form of a liquid;

(8) In the form of a gas;

(9) Other: _____.

PROCESSING

(a) The Company shall not process the PMN substance:

(1) In non-enclosed processes;

(2) Beyond the site of manufacture or import;

(3) In the form of a powder;

(4) In the form of a solid;

(5) In the form of a liquid;

(6) In the form of a gas;

(7) Other:_____.

USE

(a) The Company shall not use the PMN substance:

(1) In non-enclosed processes;

(2) Beyond the site of manufacture or import;

(3) Other than as an intermediate;

(4) Other than as a site-limited intermediate;

(5) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds _____ percent;

(6) Other than as described in the PMN;

(7) For non-industrial applications;

(8) For commercial applications;

(9) For non-commercial applications;

(10) In consumer products;

(11) In the form of a powder;

(12) In the form of a solid;

(13) In the form of a liquid;

(14) In the form of a gas;

(15) Involving an application method that generates a vapor, mist, or aerosol;

(16) Involving an application method that generates a dust;

(17) Other: _____.

DISTRIBUTION

(a) The Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who agrees in

writing to:

(1) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or _____.

(2) Comply with the same requirements, if any, required of the Company in the Protection in the Workplace section of this Order, or _____.

(3) Comply with the same environmental release requirements, if any, required of the Company in the Disposal and Release to Water sections of this Order, or _____.

(4) Comply with the same requirements, if any, required of the Company in the Hazard Communication Program section of this Order.

(5) Comply with the same requirements, if any, required of the Company in the New Chemical Exposure Limits section of this Order.

(5) Not process the PMN substance:

(i) In non-enclosed processes;

(ii) At a site not in that person's control;

(iii) Except as described in the PMN;

(iv) In the form of a powder;

(v) In the form of a solid;

(vi) In the form of a liquid;

(vii) In the form of a gas;

(viii) Other:_____.

(6) Not use the PMN substance:

(i) At a site not under the person's control;

(ii) In non-enclosed processes;

(iii) Other than as an intermediate;

(iv) Other than as a site-limited intermediate;

(v) As an intermediate where the concentration of the PMN substance in the product intended for distribution in commerce exceeds _____ percent;

(vi) Other than as described in the PMN;

(vii) For non-industrial applications;

(viii) For commercial use;

(ix) For non-commercial use;

(x) In consumer products;

(xi) In the form of a powder;

(xii) In the form of a solid;

(xiii) In the form of a liquid;

(xiv) In the form of a gas;

(xv) Involving an application method that generates a vapor, mist, or aerosol;

(xvi) Involving an application method that generates a dust.

(xvii) Other: _____.

(b) If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, the

Company shall cease supplying the substance to that recipient, unless the recipient is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(1) That the Company has within 5 working days notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (b)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(c) The Company shall distribute the PMN substance only:

(1) In mixtures in concentrations below _____;

(2) As described in the PMN;

(3) For industrial use;

(4) For commercial use;

(5) For non-consumer use;

(6) In amounts less than _____ kilograms per year;

(7) In solid form;

(8) In liquid form;

(9) In non-powder form;

(10) Other:_____

_____

(d) The Company shall not distribute the PMN substance beyond the site of manufacture.

(e)(1) Subparagraph (a) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, the effect of subparagraph (a) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substance and subparagraph (a) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR.

DISPOSAL

(a) The Company shall dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations.

(1) The PMN substance must be disposed of only by:

(i) incineration;

(ii) landfill;

(iii) deep well injection;

(iv) other: _____

_____

(2) Waste streams from manufacture must be disposed of only by:

(i) incineration;

(ii) landfill;

(iii) deep well injection;

(iv) other: _____

_____

(3) Waste streams from processing must be disposed of only by:

(i) incineration;

(ii) landfill;

(iii) deep well injection;

(iv) other: _____

(4) Waste streams from use must be disposed of only by:

(i) incineration;

(ii) landfill;

(iii) deep well injection;

(iv) other: _____

_____

(5) The Company shall not dispose of or release the PMN substance into the environment.

RELEASE TO WATER

(a) The Company is prohibited from any predictable or purposeful release of the PMN substance or any waste stream containing the PMN substance from _____ (manufacturing/processing/use):

(1) Into the waters of the United States;

(2) Into the waters of the United States without application of one or more of the following specified treatment technologies either by the discharger or, in the case of a release through publicly-owned treatment works, by a combination of treatment by the discharger and the publicly-owned treatment works:

(i) Chemical precipitation and settling;

(ii) Biological treatment (activated sludge or equivalent) plus clarification;

(iii) Stream stripping;

(iv) Resin or activated carbon adsorption;

(v) Chemical destruction or conversion;

(vi) Primary wastewater treatment;

(3) Into the waters of the United States without primary wastewater treatment, and secondary wastewater treatment as defined

in 40 CFR Part 133.

(4)(i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/ site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds _____, when calculated using the methods described in 40 CFR 721.91. However, 40 CFR 721.91(a)(4) does not apply. Instead, if the waste stream containing the PMN substance will be treated using _____, then the amount of PMN substance reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than ___ percent removal efficiency may be attributed to such treatment.

(ii) In lieu of calculating the quotient in subparagraph (4)(i), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is

denied, will explain the reasons therefore.

II. RECORDKEEPING

(a) The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(4) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Hazard Communication Program section of this Order;

(7) Copies of material safety data sheets required by the Hazard Communication Program section of this Order;

(8) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(9) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(10) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order.

(11) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured of imported.

(12) Records required by paragraph F. of the New Chemical Exposure Limits section of this Order, if applicable.

(13) Other: _____

_____

III. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

IV. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date_____

_____
Linda J. Fisher
Assistant Administrator
for Pesticides and
Toxic Substances

Date_____

_____
Name:

Title:

Company:

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

• D R A F T •

8/6/91

CO-NCELs: Generic §5(e) Order with New Chemical Exposure Limits

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

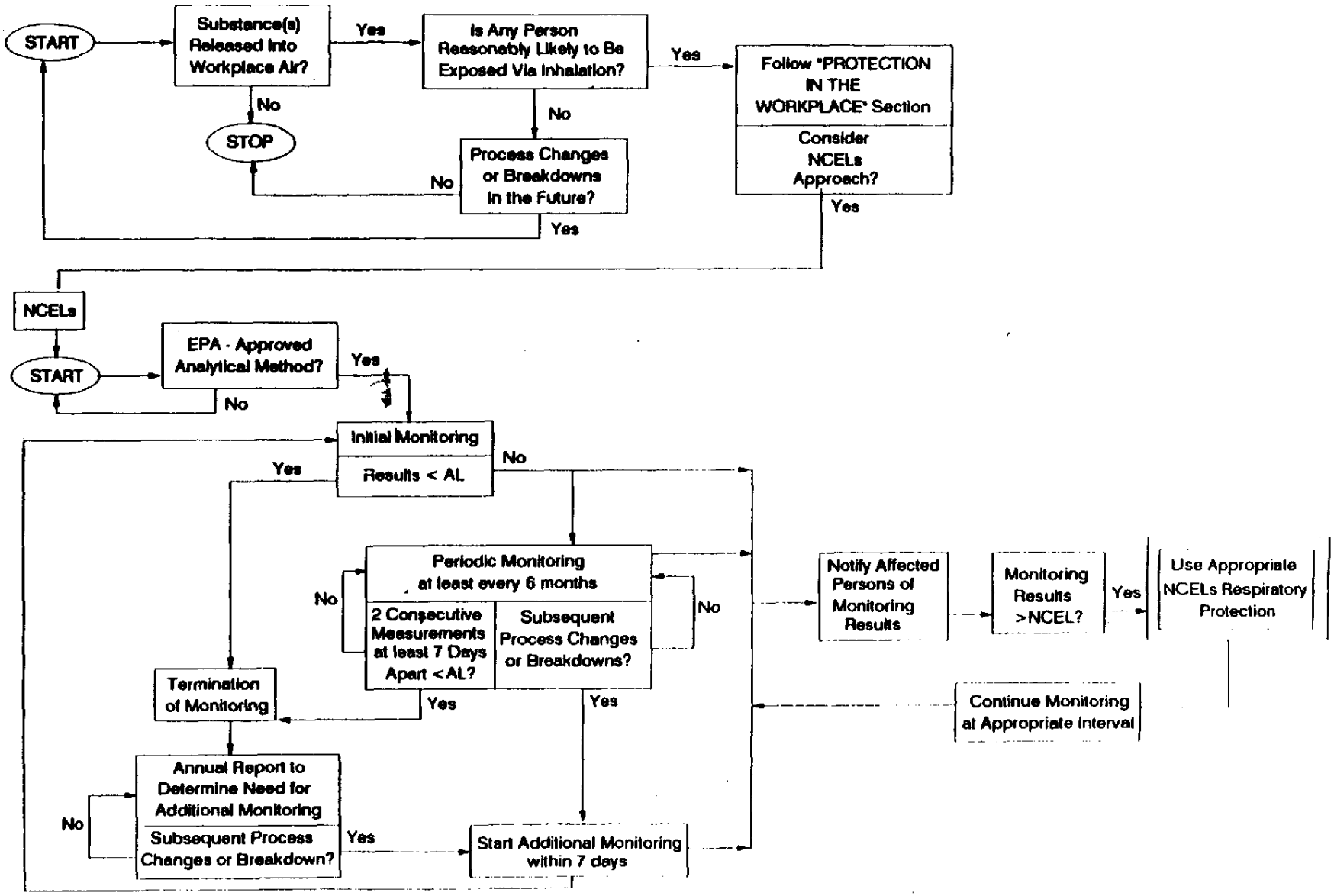
REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	**Premanufacture Notice**
	)	**Number:**
	)	
	)	
	)	
	)	
	)	
_____	)	_____
	)	
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

New Chemical Exposure Limits (NCELs) Flow Chart *



*Caveat: This chart provides a simplified illustration but does not substitute for the requirements specified in the NCELs section of a TSCA Section 5(e) Order

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