RESPONSE TO EXTERNAL COMMENTS ON NEW CHEMICAL EXPOSURE LIMITS IN TOXIC SUBSTANCES CONTROL ACT '5(e) ORDERS

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U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF POLLUTION PREVENTION AND TOXICS

NEW CHEMICAL EXPOSURE LIMITS ("NCELs")

RESPONSE TO EXTERNAL COMMENTS

CONTENTS

I. Introductory Summary

Section 5 of the Toxic Substances Control Act (TSCA) requires submission of a premanufacture notice (PMN) to the U.S. Environmental Protection Agency (EPA) at least 90-days before commencing commercial manufacture of a new chemical substance. Inhalation exposures of workers handling some of these PMN substances may present an unreasonable risk of injury. To mitigate such exposures and risks, EPA has developed "New Chemical Exposure Limits" (NCELs) provisions in Orders issued under '5(e) of TSCA.

On August 6, 1991, EPA mailed to approximately 20 external organizations draft NCELs provisions in a generic "boilerplate" TSCA '5(e) Order, along with a cover letter soliciting comments. (A copy of the 1991 draft is attached for reference in order to help readers understand some of the comments.) Since then, EPA has continued to make incremental revisions and to receive additional input from various sources, generally during negotiations of individual '5(e) Orders for specific chemicals. This "Response-to-Comments" document provides the rationale for the corresponding revised TSCA '5(e) Order NCELs provisions that were comprehensively revised and, EPA believes, improved in response to those comments from external organizations. These are standard provisions of generic "boilerplate" '5(e) Orders that can, if warranted by the facts, be modified in individual, chemical-specific '5(e) Orders.

This "Response-to-Comments" document presents (verbatim) the comments received by EPA in 1991 and EPA's responses to those comments. For each comment, an abbreviated name of the commenter appears in parenthesis. In some places, similar comments are grouped together and EPA's response appears after the last comment in such a group. The following is a list of the organizations that submitted comments and the abbreviations used herein to identify them:

Occupational Safety and Health Administration ("OSHA")

National Institute for Safety & Health ("NIOSH")

Chemical Manufacturers Association ("CMA")

Synthetic Organic Chemical Manufacturers Association ("SOCMA")

Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry ("ETAD")

The Society of the Plastics Industry ("SPI")

Laborers' Health and Safety Fund of North America ("Labor")

Amalgamated Clothing and Textile Workers Union ("ACTWU")

American Industrial Hygiene Association ("AIHA")

The following is a brief summary of the comments and EPA's responses:

A. Inter-Agency Jurisdiction & Coordination

Comment Summary: EPA should coordinate with other agencies having expertise in worker protection. Where does EPA's jurisdiction end and OSHA's begin?

Response Summary:

- EPA has ongoing communication with OSHA and NIOSH on worker protection issues and has solicited input on the NCELs program.

- EPA has sought to make its program consistent with OSHA's wherever possible. EPA's NCELs provisions are modeled after OSHA PELs and comprehensive standards, and now match OSHA's program even more after NCELs revisions in response to public comments.

- There will generally be no overlapping regulation of new chemicals, because EPA's NCELs apply to new chemicals with little or no data, so risk assessment is generally based on analogue data from similar substances. EPA added an explicit sunset provision to its '5(e) Orders which states that the NCEL and respirator requirements are automatically nullified if OSHA promulgates a PEL for the same substance. EPA may raise NCELs cases to the attention of OSHA and NIOSH, in the unlikely event that such is warranted by the toxicity data and production volume associated with the new chemical substance.

B. Standard Setting

Comment Summary: EPA's method for setting NCELs concentrations should not be based on such limited data, should parallel OSHA's, should be published for comment, and should allow for prompt modification in response to new data.

Response Summary:

- EPA is publicizing its method for setting NCELs concentrations.

- On a case-by-case basis, EPA will consider setting NCELs concentrations based on OSHA PELs and American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), and will consider economic and technological

feasibility, especially in cases where there is sufficient evidence that the new chemical may present less risk than existing substances which the new chemical may replace.

C. Analytical Method

Comment Summary: The NCELs analytical method criteria and requirement for EPA approval are inconsistent with OSHA, overly burdensome, and discourage adoption of the NCELs approach. EPA should, like OSHA, set a performance-based standard for accuracy of, for example, ± 25% of the NCEL concentration with a confidence level of 95%.

Response Summary:

- EPA replaced the requirement that EPA must approve the company's analytical method with, instead, a requirement for verification by an independent third-party laboratory.

- EPA adopted OSHA's performance standard of ± 25% accuracy with 95% confidence.

- Consistent with OSHA and NIOSH requirements, EPA raised the lower quantitation limit from 0.1 times the NCEL to half the NCEL, and reduced the minimum upper quantitation limit from 2,000 times the NCEL to twice the NCEL. However, the method should cover the expected exposure range and, if a monitoring sample exceeds the UQL by >10%, workers must wear 19C air-supplied respirators.

- For analytical method verification and subsequent monitoring, EPA will accept use of a laboratory accredited by the American Industrial Hygiene Association (AIHA) as an alternative to compliance with TSCA Good Laboratory Practice Standards (GLPS). Other comparable programs may be used, if approved in advance in writing by EPA.

- EPA clarified that certain analytical method requirements apply only to method development/validation and not to subsequent monitoring.

- EPA eliminated the cumbersome "Contents of Submission" requirement that referenced the October 1987 OTS Guidance Document for the Preparation of Quality Assurance Project Plans.

D. Monitoring Requirements

Comment Summary: The NCELs monitoring requirements are unnecessarily more burdensome than OSHA's/not stringent enough.

Response Summary:

- EPA added an exemption from the monitoring requirements based on documented and reliable objective data when exposures are obviously so low that monitoring is unnecessary.

- For batch production processes of short durations, EPA reduced the number of days between certain monitoring results required to entitle a company to reduce respiratory protection or terminate monitoring.

- EPA deleted the requirement for an annual **report** to determine the need for additional **monitoring** after termination of monitoring. OSHA does not require this. EPA is deleting only the reporting requirement, not the monitoring requirement.

- EPA increased monitoring frequency from every 6 months to every 3 months when samples measure above the NCEL.

E. Recordkeeping

Comment Summary: The NCELs recordkeeping requirements are unnecessarily more/less burdensome than OSHA's.

Response Summary:

- EPA has attempted to keep recordkeeping requirements to the minimum essential to maintain credible enforcement capability.
- Since existing OSHA regulations already require these employee exposure records to be kept for 30 years, EPA is doing likewise.

F. "Hierarchy of Controls"

Comment Summary: EPA should impose a mandatory "Hierarchy of Controls" whereby respirator usage should be allowed only after attainment of the NCEL via engineering controls and work practices is determined unfeasible.

Response Summary:

- To allow flexibility for new chemicals manufactured in small batches with few workers, EPA (unlike OSHA) will not mandate

"Hierarchy of Controls"; however, EPA's '5(e) Orders expressly state a preference for source reduction and engineering controls over respirators.

II. INTER-AGENCY COORDINATION

1. Comment (AIHA): AIHA suggests that one federal agency should have regulatory jurisdiction and developmental authority for workplace exposure limits. The NCEL proposal crosses jurisdictional boundaries with OSHA and NIOSH in a way that could be duplicative and counter-productive for the health and safety of workers. Traditionally the agency with the power to establish workplace exposure limits has been OSHA with scientific support from NIOSH and other sources in the public and private sector.

AIHA suggests that confusion and inconsistency will result if two agencies of the government regulate in the same area. Clear authority should be given to one agency to avoid two sets of standards for similar compounds resulting in a risk benefit debate among affected parties. AIHA suggests adoption of one of the following alternatives.

- o EPA should defer to OSHA and NIOSH for NCEL standard setting altogether.
- o Alternatively, EPA should adopt OSHA criteria for workplace exposure standard setting so that all factors of cost, risk, feasibility, and toxicology are considered in the arduous, but necessary, OSHA permissible exposure limit process (AIHA makes this last suggestion on the basis of the extensive experience of OSHA in standard setting in an effort to maintain fair, consistent and reasonable exposure limits with which all affected parties can live.)
- o Alternatively, EPA could rely on voluntary workplace standard setting organizations such as the AIHA Workplace Environmental Exposure Limits (WEEL) Committee and the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) Committee for assistance in the NCEL process.

The AIHA WEEL Committee and the ACGIH TLV Committee have extensive experience with workplace exposure limit setting that could lend third-party objectivity and assist in expediting the process of setting exposure limits for new substances. AIHA would be willing to discuss such a role for its WEEL Committee with EPA, OSHA and NIOSH.

AIHA suggests that EPA and the Department of Labor (OSHA) and Health and Human Services (NIOSH) work in total cooperation on all aspects of this regulation relating to worker safety and health. For clarity to EPA, OSHA, and private sector personnel who must interpret and carry out this rule, AIHA suggests that once cooperative agreement on provisions that extend beyond the 29 CFR 1910 worker protection rules is reached with OSHA these extra

provisions should be (1) highlighted in italics or some other fashion in the actual text of the rule and (2) placed in a table for side by side comparison of TSCA Section 5(e) worker protection requirements versus standard OSHA 29 CFR 1910 workplace regulations.

2. Comment (CMA): EPA should coordinate with those agencies and organizations that have been established to deal specifically with occupational health and safety issues. Adding EPA to the "universe" of organizations that sets permissible exposure limits will lead to confusion and potential inconsistencies in the workplace. EPA should take full advantage of the expertise of other groups in developing occupational permissible exposure limits. The following federal agencies and institutions are charged with protecting the health of workers: the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), the American Conference of Governmental Industrial Hygienists (ACGIH), the American Industrial Hygiene Association (AIHA) and the American National Standards Institute (ANSI). In embarking on this effort, the Agency should strive to involve, or at least learn from, the agencies and institutions, especially OSHA, which possess the required technical expertise and experience necessary to either set a standard or recommend guidelines. The historical experience of these groups adds critical perspective to developing, administering and enforcing NCELs.

EPA should consider certain questions before proceeding further with the proposed NCELs program. What avenues of communication must be established between EPA and other workplace-directed agencies or institutions? Should an external consultant, such as an appropriate OSHA representative, be enlisted to help establish NCELs or, at the very least, to assist in formulating procedures and policies to be used by EPA?

EPA should coordinate more closely with other Agencies that have worker protection expertise. The Agency should take full advantage of this expertise in developing occupational permissible exposure limits and not set limits that will lead to confusion or inconsistencies in the workplace.

3. Comment (SOCMA): SOCMA believes that EPA should limit the scope of its NCELs program, and should defer to the longstanding authority and expertise of OSHA on the establishment of workplace exposure limits. Much of industry's concern would be alleviated if EPA postponed implementation of the NCELs program until it develops a mechanism to address adequately the following: (1) coordination of EPA's efforts under the new chemicals program with the existing efforts of OSHA with respect to the establishment of exposure limits for chemicals, and (2) transfer of responsibility for

workplace exposure from the NCELs program to OSHA at the earliest appropriate time.

SOCMA certainly applauds EPA's goal to prevent potential unreasonable risk to workers via inhalation exposure to chemical substances subject to Section 5(e) Orders or SNURs. However, SOCMA believes there is considerable risk that EPA's proposed approach -- involving the Agency's independent development of workplace exposure limits -- will infringe on the longstanding jurisdiction of OSHA over workplace safety and health conditions, and could result in conflicting and burdensome requirements for industry.

Second, we are concerned that EPA's foray into the area of setting workplace exposure limits will result in conflict between EPA and the Occupational Safety and Health Administration ("OSHA") concerning their respective jurisdictions over worker health and safety, and could result in complex, conflicting and burdensome requirements for industry.

The proposal also leaves unclear the effect that placement of the new chemical on the TSCA Inventory would have on the requirements of the NCELs program in the absence of OSHA regulation. Does EPA intend that the requirements of the NCELs program cease immediately (and automatically) upon termination of a Section 5(e) Order or SNUR? Does EPA plan to coordinate its NCELs effort with OSHA, in order to ensure that EPA and OSHA do not establish conflicting requirements pertaining to hazard communication, recordkeeping and reporting of workplace exposure information?

4. Comment (CMA): Finally, EPA should clarify the extent to which it will relinquish authority for regulating workplace exposure to new chemicals after the completion of PMN review. At what point does a chemical and its associated NCEL come under OSHA's authority (that allows the establishment of a new permissible exposure limit)? This problem must be addressed by EPA and OSHA in a cooperative effort, and reinforces the need for OSHA's involvement in the process of establishing NCELs.

5. Comment (SPI): It is unclear from the draft when EPA's NCELs end or when OSHA begins to assume regulation responsibilities. This program covers new chemicals which at some date become existing/old chemicals. It would appear that the enforcement responsibility on regulatory authority should pass to OSHA at some date. It is not clear from the proposal when this may occur.

If EPA believes that the chemical in question is a health hazard, then the Agency should make the appropriate report to OSHA under Section 9 of TSCA so as to avoid unnecessary duplication of regulations. Any substance which is subject to the requirements of an OSHA standard would presumptively not be an unreasonable risk with respect to communication of hazards because OSHA's rule is expressly intended to eliminate such risks. EPA could simply make

the statement that the substance should be considered a health hazard for purposes of the OSHA standard and that manufacturers should prepare Material Safety Data Sheets and labels accordingly.

6. Comment (SOCMA): EPA's general proviso that it "could revoke or modify the NCEL" in the event of OSHA regulation of workplace exposure leaves a number of significant questions unanswered, and leaves industry threatened with potentially conflicting OSHA and EPA requirements. For example, the NCELs program is intended to apply only to new chemicals that are not otherwise regulated by EPA or other federal agencies. Therefore, by its terms there are no circumstances that would support EPA's proposal that it "modify" an NCEL in the face of OSHA regulation; in such an instance, EPA should withdraw the NCEL. In fact, any Section 5(e) Order or SNUR containing an NCEL should include a "sunset" provision that would automatically terminate the NCEL in the event of OSHA (or other federal agency) regulation.

7. Comment (ETAD): Further, NCELs should be accompanied by sunset provisions that would be triggered automatically, for example, when an exposure limit is established by OSHA. Such procedures, if properly established, could ensure that any NCELs reflect the most up-to-date scientific information available, with minimum burden on EPA's and industry's resources.

8. Comment (ACTWU): These differences create potential conflicts between EPA and OSHA when regulating very similar circumstances. I think it is imperative that EPA tailor its NCEL activities to complement those of OSHA rather than to act as if the NCEL is the "only game in town". Otherwise employers, unions and workers will be confronted with a difficult, and sometimes impossible, choice between which rule to follow.

I believe that there is a relatively simple way to prevent these conflicts and assure that coordinated efforts between the two agencies maximize the efforts of all parties to protect workers. EPA should continue to use its authority under the TSCAct to refer to OSHA issues of hazardous exposures where the data justify it. In addition, where the data are lacking to justify regulation at the time, EPA should assure that sufficient data are gathered as soon as possible to allow either agency to adopt whichever regulations offer the most protection.

OSHA Reform

Finally, many of these issues are dealt with in the Comprehensive Occupational Safety and Health Reform Act which is now pending before the Congress. I strongly urge EPA to review this legislation in detail, including the provisions for standard setting (Title IV). This title offers an explicit role for EPA in OSHA's standard-setting process, as well as many other improvement relevant to the NCEL process. This legislation has a "reasonable"

chance of passage (to borrow a phrase) and your efforts should take this into account. Indeed, I think it is incumbent upon the Office of Toxic Substances to inform the Congress of the potential benefits offered by this legislation in resolving the problems to which the TSCAct is addressed.

EPA Response: In general, EPA's NCELs fill a unique niche not occupied by OSHA's PELs. By statute, the factors which must be considered by EPA and the burden of proof applicable to NCELs under '5 of TSCA are different from those applicable to OSHA PELs under '6 of the OSH Act. When enacting TSCA in 1976, Congress designed '5 to regulate risks from new chemicals before they enter commerce. TSCA '5 requires manufacturers of new chemicals to submit a pre-manufacture notice (PMN) to EPA at least 90-days before commencing manufacture for commercial purposes. Under '5(e) of TSCA, if EPA finds that "**information available to [EPA] is insufficient** to permit a reasoned evaluation of the health and environmental effects of a chemical substance" and the substance "**may present an unreasonable risk** of injury to health or the environment," EPA may issue an Order to "prohibit or limit" activities associated with the substance. However, TSCA does not require manufacturers of new chemicals to develop any toxicity test data for submission with the PMN. Therefore, to assess the risk from a new chemical, EPA often must rely on toxicity data on existing chemicals with molecular structures similar to the new chemical. EPA can use this same analogue data to set NCELs concentrations when there is a defined health endpoint and EPA believes the new chemical is not significantly more toxic than its analogue.

Because EPA's NCELs apply to uncommercialized new chemicals with little or no data, EPA and OSHA will generally not simultaneously regulate the same substance. EPA may refer to OSHA former new chemical substances subject to a NCEL, if additional data is received regarding toxicity and exposure such as to increase evidence of risk. Most likely, OSHA will not regulate a PMN substance unless and until (1) the new chemical becomes more widely commercialized with increased human exposures and (2) toxicity data on the chemical is developed showing adverse health effects. If so, OSHA could consider the new data in deciding whether to adopt EPA's NCEL or set a different exposure limit. EPA has added an explicit sunset provision to its '5(e) Orders which states that the NCEL and respirator requirements are automatically nullified if OSHA promulgates a PEL for the same substance.

Thus, there are a few areas where differences between EPA's New Chemicals Program under section 5 of TSCA and OSHA's PEL program under the Occupational Safety and Health Act necessitate different treatments and different regulatory requirements. For example, there usually is no established analytical method for measurement of the new chemical substance. Thus, EPA imposes more

detailed requirements for accuracy and precision, and requires verification of the company's method. Also, EPA does not impose a mandatory "Hierarchy of Controls." To allow flexibility for new chemicals manufactured in small batches with few workers, the company may elect, as an alternative to the NCELs provisions, to use respirators specified by EPA based on exposure estimates without actual monitoring data. However, EPA's '5(e) Orders expressly state a preference for source reduction and engineering controls over respirators.

EPA recognizes both the long-standing expertise of OSHA and NIOSH in the area of worker protection, and the wide-spread applicability of existing OSHA regulations to the workplace. Therefore, EPA has made every effort to copy OSHA's exposure limits provisions wherever appropriate. Consequently, in general, EPA considers the body of law and guidance documents on OSHA's PELs as relevant to resolving questions on interpretation of EPA's NCELs provisions.

The various federal agencies involved with regulating workplace safety do communicate and coordinate regularly. EPA meets monthly with OSHA and NIOSH through the ONE (OSHA/NIOSH/EPA) Committee to coordinate on various subjects of mutual interest. EPA has solicited comments specifically on NCELs from OSHA and NIOSH (including the August 1991 NCELs draft) and agency representatives have met on several occasions specifically to discuss EPA's NCELs. As reflected herein, OSHA and NIOSH have submitted some written comments on NCELs, generally relatively minor or technical in nature. OSHA and NIOSH have both acknowledged the critical role of EPA's NCELs program in setting exposure limits for new chemicals with limited data (See, e.g. "Understanding EPA's New Chemical Exposure Limits Program," The Synergist, American Industrial Hygiene Association, Fairfax, Virginia, April 1995, p.6).

Lastly, given both the short 90-day statutory review period and the obligation to protect confidential business information (CBI) imposed on EPA, it would be inappropriate and impractical for EPA to involve private organizations such as the ACGIH TLV Committee and the AIHA WEEL Committee in setting NCEL concentrations in individual chemical specific cases. Not only would this add severe delay to the PMN process and appear to abdicate governmental responsibility, but associated problems would be raised concerning protection of TSCA CBI, particularly since many members of these committees are employees of competing private chemical manufacturing companies.

III. ESTABLISHMENT OF THE NCEL

1. Comment (SOCMA): One of the major concerns of SOCMA members is EPA's intention to establish NCELs for new chemical substances for which no or little analytical data exist pertaining to the potential risk associated with workplace exposure. Currently, the setting of exposure limits by federal agencies (such as OSHA) is a deliberative, thorough process, based on data and evidence of risk. EPA's proposal to establish numerical exposure limits in the absence of adequate data would undermine the credibility and value of the standard-setting process and would result in the establishment of limits that are without scientific foundation and are therefore by definition arbitrary.

2. Comment (ETAD): First, ETAD believes that establishing numerical exposure limits based on little or no relevant information would be detrimental. The process by which OSHA sets exposure limits is a thorough and deliberative process based on detailed risk information. Attempting to set exposure limits in the absence of such information would be arbitrary and could undermine the credibility of other standard-setting activities.

EPA Response: EPA is required by TSCA to review PMNs and to prevent unreasonable risks which may result from those To mitigate potential unreasonable risks from operations involving new chemicals, EPA may issue TSCA '5(e) Orders that set controls on those operations. Such controls may take the form of required respirator use or inhalation exposure limits. EPA is establishing NCELs in recognition of a general consensus among industry, labor, the scientific community, and government agencies that using engineering controls and monitoring to meet inhalation exposure limits is generally preferable to using respirators to mitigate risks from inhalation exposures to toxic chemicals.

EPA's method of setting NCEL concentrations is consistent with EPA's past and current methods of assessing the potential risks of new chemical substances. Most PMNs provide little or no data toxicity data on the PMN substance itself. Therefore, from the inception of its New Chemicals program, EPA has often relied on toxicity data on other chemicals with molecular structures similar to the PMN substance to develop a Structure Activity Analysis (SAR). Under this approach, EPA first identifies and reviews the test data available for analogues and/or chemicals predicted to be key metabolites of the new chemical substance. Then EPA uses SAR to apply the results of the review to the new chemical substance.

EPA has used this procedure to establish current NCEL concentrations. The current NCEL provisions clearly state that these NCEL concentrations are "interim levels determined by EPA based on the limited information available to the Agency at the time of development of the Order." Nevertheless, EPA does perform a careful review of all available data, including analogue data, to

select an appropriate NCEL level. If adequate data to determine a NCEL concentration for a particular chemical are not available, EPA will not establish a NCEL for that substance.

As the preceding discussion makes clear, NCEL concentrations based on relatively complete data are likely to reflect the high quality of that data. In contrast, when PMN submitters do not submit data adequate to address unreasonable risk issues within the 90-day review period, NCELs for those substances may be based on limited information. EPA encourages companies to include relevant data -- such as chronic or subchronic toxicity studies on close analogues -- in their PMN submissions. (As discussed below, companies should also provide information on relative risk and feasibility.) With this data, EPA and the PMN submitter will be better able to establish in the initial Consent Order a NCEL more closely tailored to the actual risk presented by the PMN substance. Alternatively, if additional data become available after establishment of the NCEL, the regulated company may petition EPA to change the NCEL in accordance with the Modification section of the '5(e) Order.

3. Comment (CMA): We also believe that the exposure limits EPA intends to develop will be overly protective, be more restrictive than OSHA's standards for analogous existing substances, discourage companies from exercising the NCELs option, and result in continued reliance on respirators to control new chemicals of concern.

EPA's procedures for developing and implementing NCELs must be streamlined if the positive objectives of the NCELs concept are to be realized.

4. Comment (CMA): EPA's framework for establishing NCELs should parallel OSHA's process for setting PELs to the greatest extent possible. In most instances, the driving force for a consent order under Section 5(e) will be structural similarities between the new substance and an analogous existing chemical. Since the new substance will be regulated because it may have the same health concerns as the analog, the workplace exposure limits for the two chemicals should be identical. When an OSHA PEL exists for the analog, it should be the basis for the NCEL.

If no PEL exists for the analog, EPA should base the NCEL on the Threshold Limit Value (TLV) set by ACGIH. In the absence of a PEL or TLV, or if the PMN chemical would fall under the OSHA dust standard or another generalized OSHA standard, the NCEL should be derived using established OSHA scientific criteria and methodology for determining "significant risks."

EPA Response: For reasons explained elsewhere and highlighted in the Introductory Summary outlined above, EPA believes that the new NCELs provisions have been streamlined and improved in response to

the external comments received. EPA does indeed wish to promote the NCELs approach and hopes that the new provisions will be utilized by industry.

Whenever there is a PEL or TLV for an analogue chemical substance, EPA will review the underlying basis for that number. EPA may conclude that the PEL or TLV is sufficiently protective. However, EPA may also have additional data on the new chemical substance as well as other similar analogues, and when accounting for feasibility in risk management decisions, may determine that adherence to the PEL or TLV may result in an inadequate level of worker protection for the new chemical substance. By statute, the factors which must be considered and the burden of proof applicable to EPA's NCELs under '5 of TSCA are different than those applicable to OSHA PELs under '6 of the OSHA Act, particularly with regard to issues bearing on feasibility. (See EPA's next Response to Comment regarding feasibility).

5. Comment (CMA): EPA's NCELs determinations should also consider feasibility. Under the Occupational Safety and Health Act, OSHA cannot set an exposure limit that is technologically or economically infeasible. EPA should also establish exposure limits that are within the bounds of feasibility. During consent order negotiations, EPA should consider feasibility data provided by the PMN submitter for its own and its customers' operations. Subsequently, when a Significant New Use Rule (SNUR) is developed for the Section 5(e) substance, EPA should consider the feasibility concerns of other manufacturers and processors. The TSCA new chemicals program should not impede innovation of new products.

EPA Response: As a matter of law, the congressional mandate reflected in TSCA '5 gives EPA broad authority to establish restrictions on new chemicals based on a finding of potential unreasonable risk provided there is no significant loss of benefits to society from issuing the Consent Order. As a matter of policy, EPA will consider feasibility arguments (such as how the concentration that EPA establishes as the NCEL should be influenced by the company's technological capability to attain and detect that level) on a case-by-case basis. In such cases, EPA encourages the submission of data to support feasibility concerns.

Technological and economic feasibility of meeting an exposure limit will be a key consideration in "safer substitute/relative risk" cases where the company provides EPA with sufficient evidence that a new chemical substance is a desirable replacement for a more hazardous existing chemical. For such cases, EPA will strive to set a NCEL for the new chemical at a level that not only protects human health but also is feasible for the manufacturer. The Agency is very interested in working with industry to achieve net risk reduction.

6. Comment (CMA): In its August 6, 1991, letter to CMA, EPA maintains that "[t]he NCELs provisions are modeled after the permissible exposure limits (PELs) promulgated by the OSHA at 29 C.F.R. Part 1910 pursuant to Sections 6(a) and 6(b) of the Occupational Safety and Health Act." Nonetheless, EPA's description of the proposed NCELs program contains no information concerning the methodology EPA intends to use to set exposure limits. The Agency should provide detailed information concerning the methodology it intends to use for setting exposure limits.

7. Comment (SOCMA): Our concern over EPA's proposal to establish workplace exposure limits is intensified by the fact that EPA has provided no suggestion in the draft Order as to how it plans to develop NCELs, even in the unusual circumstance where adequate data on risk are available for the chemical substance. Despite a brief, informal statement that "the NCELs provisions are modeled after the permissible exposure limits (PELs) promulgated by [OSHA]," the text of the generic '5(e) Order itself, specifically Part C (see draft Order at 22), contains no details of the methodology EPA plans to use to establish NCELs.

8. Comment (ETAD): Prior to instituting its proposed program, EPA should establish and publish for comment its methodology for establishing NCELs. Such methodology should include: (1) identification of the data to be considered in establishing NCELs; (2) procedures for derivation of NCELs; (3) guidelines for a determination that data are inadequate to support issuance of an NCEL; (4) procedures for modifying NCELs based on development of additional data; and (5) mechanisms for affected parties to provide input to the process and to petition for modification of NCELs.

9. Comment (Labor): EPA will establish the new chemical exposure limits as TWA's and STEL's [C(1) and (2)]. This approach places a substantial burden on EPA with regard to worker protection, particularly in view of the limited data available on most new chemicals. The EPA methodology for establishing such limits should, therefore, be written, peer reviewed, and made available to anyone who requests it.

EPA Response: EPA's methodology for setting NCELs concentrations is attached as Attachment I.

10. Comment (SOCMA): It is unclear from the draft section 5(e) Order whether EPA will consider data on chemicals similar to the new chemical substance (e.g., analogues) for purposes of establishing NCELs, or whether the Agency intends to require testing of the individual chemical substances.

EPA Response: EPA generally regulates new chemical substances based on analogue data without data on the PMN substance itself, and NCELs will be handled likewise. Please refer to EPA's earlier response addressing standard setting.

11. Comment: EPA also should create procedures for modifying NCELs based on development of additional data, and should provide affected parties with a specific mechanism to provide this data voluntarily and to petition the Agency for a prompt modification of NCELs. This would ensure that any NCELs established reflect the most up-to-date scientific information available, with the minimum burden possible placed on EPA's administrative resources. Such methodology and procedures should be developed and incorporated into EPA's draft proposal.

12. Comment (SPI): EPA says if more data becomes available, the Agency could revoke or modify the NCEL. There should be a procedure for this review including a time limit and "hammer" provisions if EPA fails to act (p. 3 cover letter).

13. Comment (CMA): A mechanism is needed to assure that, when new test data are available on Section 5(e) chemicals, the applicable NCEL will be promptly modified or eliminated. An increasing number of Section 5(e) Orders include testing requirements designed to develop data on the end-points identified by EPA on the basis of structural similarities. Often, the resulting data will show that the new chemical is less toxic than the EPA-identified analog. In these instances, prompt reconsideration of the NCEL will avoid overly protective and stressful employee workplace controls.

EPA Response: All TSCA '5(e) Orders contain a "Modification and Revocation" section with provisions authorizing such modifications or revocations based on new information. EPA will consider test data received on the new chemical substance and other information bearing on the risk associated with the substance, and will modify or revoke the NCEL if the data evaluation changes EPA's determination of potential unreasonable risk. Such modifications or revocations will be drafted in accordance with the New Chemical Program's (NCP's) general policy which evaluates cases and requests in the order in which they are received. The NCP is engaged in an ongoing process to streamline its new chemical review to expedite such decisions.

14. Comment (CMA): In developing a methodology for NCELs, EPA should also clarify the conditions under which a Short Term Exposure Limit (STEL) will be established. For many new chemicals, STELs will be unwarranted. Where the driving force of a Section

5(e) order is chronic health concerns based on structural similarities, these concerns will be best addressed by a PEL. STELs should be limited to situations where the new substance is known or suspected to present an acute health hazard or where short-term peak exposures are known or suspected to contribute to the risk of chronic health effects. ACGIH has backed away from setting STELs except in these situations. EPA should be consistent in its new chemicals program.

EPA Response: Most NCELs will be based on chronic endpoints, and consequently the average exposure over time is more important than acute exposure. EPA concurs with CMA's comments regarding STELs. EPA anticipates establishing STELs only in cases where there is a potential acute health hazard, or, in CMA's words, "where short-term peak exposures are known or suspected to contribute to the risk of chronic health effects." In other cases, the STEL provisions will be deleted from the section 5(e) Order. To date, EPA has not issued a '5(e) Order containing a STEL.

IV. ANALYTICAL METHOD

A. Method Approval by EPA

1. Comment (SPI): EPA should not require companies to submit analytical methods to EPA for approval. The approach suggested by OSHA in its health standards, that the method be demonstrably accurate and precise within specified limits is more appropriate because it is a performance standard rather than a specification standard. So long as accuracy and precision are maintained, the means by which the results are achieved are of no consequence to the regulator. The current NCEL approach is reflective of a bias in EPA for standard methods. Currently, OSHA rules specify +/- 25% precision and a 95% confidence level and that the accuracy of the method be documented. See for example, the benzene standard, 29 CFR 1910.1001(d)(6).

2. Comment (CMA): The extensive and extremely detailed sampling, analytical and monitoring requirements of the NCELs program are too burdensome. As a result, very few companies, particularly small to mid-size ones, will choose to exercise the NCELs option as currently written. The requirements should be streamlined and mandate a performance-oriented approach that parallels comparable OSHA standards.

3. Comment (CMA): Before a NCEL can be implemented, EPA's draft consent order would require Agency review and approval of the analytical methods developed by the PMN submitter. This

requirement will greatly add to the workload of industry and EPA analytical chemists. It is estimated that as many as 200 person-hours over a period of 180 days are necessary for method development, validation and submittal. The introduction of engineering controls in lieu of respirators could also be delayed for a considerable period if EPA does not complete its review promptly. Should the Agency acquire additional information about a proposed analytical method or should the internal EPA review process become protracted, PMN submitters and their customers may have no choice but to implement respirator programs and to abandon plans to install engineering controls if initial monitoring shows they are necessary.

OSHA standards do not mandate Agency approval of analytical methods. Rather, they simply establish minimum requirements for the reliability/reproducibility of such methods. As a result, employers have the latitude to develop and validate methods of their own, meeting the general OSHA criteria. NIOSH already has established analytical methods, while AIHA has accredited laboratories to perform the analyses. Incorporation of this approach into the NCELs program would provide similar flexibility and performance orientation to companies subject to Section 5(e) Orders.

4. Comment (CMA): Further flexibility could be achieved by allowing PMN submitters to adopt established analytical methods developed by NIOSH or other recognized sources for analogous existing chemicals where the methods can be expected to be used reliably for the new substances. In such situations, the submitter should be relieved from the requirement of developing a new analytical method when the submitter can document that an existing method is known to provide valid data for the new substance. Given the substantial effort required to develop new analytical methods, the absence of this option could create major disincentives to participate in the NCELs process.

5. Comment (CMA): Does EPA intend to review sampling strategies before companies begin data collection? CMA recommends that general analytical laboratory and sampling plans be acceptable to avoid unnecessary delays and costs. Our member company analytical chemists express considerable concern about EPA's specification for newly developed industrial hygiene sampling and analytical methods. EPA's specification requires that a method be usable across a range of 2×10^4. Typical laboratory requirements, however, dictate a range of 1×10^2. Specification for sampling and analytical requirements should state the accuracy and precision required rather than reliance on "approved" methods.

EPA Response: EPA is no longer requiring agency review and approval of the company's sampling and analytical method. Instead, the company must submit its method to an independent third-party laboratory for verification of the company's method validation data. EPA believes this is necessary to ensure that there is an adequate analytical method with which to accurately measure workplace concentrations of a new chemical substance. EPA has also revised the NCELs provisions to allow use of an AIHA accredited lab as an alternative to compliance with TSCA GLPS, and to clarify that many of the analytical method requirements in the NCELs provisions apply only to method development/validation but not to subsequent monitoring. This more performance-based approach has been developed based on the NIOSH and OSHA method development criteria currently applicable to the chemical industry (see Attachment II - List of References). Similarly, EPA does not review sampling strategies, but rather has established monitoring requirements modeled closely after OSHA requirements. EPA expects that the NCELs revisions minimizing inconsistencies with OSHA requirements will make NCELs more feasible for companies to use.

B. Method Quantitation Range

1. Comment (NIOSH): NCEL quantitation limit (NQL) (page 16): The NCEL definition of "quantitation limit" proposes a new term different than the usual analytical definition of "limit of quantitation" (LOQ) used by the American Chemical Society (ACS) and NIOSH chemists. To avoid confusion with existing usage, a term other than "quantitation limit" should be specified. It appears that what is really being specified by EPA are precision and accuracy requirements covering a range of 0.1 to 2,000
time the NCEL. Is it necessary to specify precision and accuracy up to 2,000 times the NCEL? What happens if the method cannot meet this requirements?

2. Comment (OSHA): Since the type of respiratory protection required is based on concentration thresholds greatly above the NCEL, I understand the reason for the requirement in section B.(4)(i) that the analytical method be capable of quantifying the new PMN substances from the NQL through 2,000 times the NCEL. The ability to measure concentrations over such a wide range may be restricted in many cases by limited flexibility in the sampling procedure.

3. Comment (CMA): An NQL of 2 or 3 levels below the NCEL should be sufficient, especially if the detection limit signal to noise ratio is set at five to one. If the NCEL is set at a ppb level, it will be impossible to reach an order of magnitude below the NCEL, particularly for short-term samples.

4. Comment (SPI): Page 16 (4)(i) - EPA should define and provide justification for "one order of magnitude."

5. Comment (SPI): Page 16 - It is unclear why the difference of the NQL and the NCEL doesn't vary with the magnitude of the NCEL.

EPA Response: EPA's original requirement for the method to be capable of quantifying the PMN substance up to 2,000 times the NCEL was included to ensure the analytical method would be reliable at higher concentrations where 19-C air-supplied respiratory protection (with a NIOSH Assigned Protection Factor (APF) of 2,000) may be necessitated by the monitoring results. For lower concentrations, EPA based the frequency of monitoring upon the action level (AL = 0.5 NCEL). Thus, the method must be reliable below the action level. One order of magnitude below the NCEL was considered reasonable to ensure a practical yet smaller range around the AL.

EPA has changed the NCELs provisions to state that the analytical method should be able to reliably quantify concentrations across the full range of expected exposures. At a minimum, the method must have a lower quantitation limit of one half the NCEL (instead of 0.1 x NCEL) and an upper quantitation capability of twice the NCEL (instead of 2,000 x NCEL). This new range is consistent with existing OSHA rules. If, however, the company obtains a monitoring sample that is more than 10% above the upper quantitation limit of the analytical method, exposed workers must wear a 19-C supplied-air respirator. Of course, the company may decide to use a self-contained breathing apparatus (SCBA) when very high exposures are present due to emergency or other conditions (see paragraphs (d)(5) and (e)(2) of the revised '5(e) Order provisions).

C. Method Performance Requirements

1. Comment (NIOSH): Paragraph (4)(iv) (page 17); Specifies spiking at 0.5, 1.0, and 2.0 times the NCEL to determine the percent recovery. NIOSH methods development procedures also call for spiking at 0.1 times the selected level.

2. Comment (NIOSH): Precision - relative difference: The calculation of relative percent difference (RPD) is not complete. The resulting value from the calculation should be multiplied by 100. RPD does not convey much information about method precision. A method with an RPD of 40% would have a relative standard deviation (RSD) of 27.9%. This is not very precise.

3. Comment (NIOSH): Calculated percent recovery: What is meant by controlled environment? The number of samples specified for calculating percent recovery do not provide much statistical power for assessing percent recovery. During method development, at least 5 matrix spikes should be run each at 0.5 NCEL, at NCEL, at 2 times NCEL. It also would be useful to run 6 spikes at the NQL. (This range does not agree with the range specified on page 16.) During method development, the calculated percent of recovery is to be determined by at least 7 matrix spikes over the range 0.5 to 2 times the NCEL. This range does not agree with the range specified on page 16. Specifications for the recoveries of matrix spikes analyzed during subsequent monitoring also should be stated.

4. Comment (NIOSH): Desorption efficiency and sample storage study (pages 18-19): How does "desorption efficiency" differ in principal from "calculated percent recovery?" The requirements for storage studies do not specify the length of storage (e.g., for 30 days to accommodate sample shipment and lab delays).

5. Comment (OSHA): Section B.(4)(iv) states that the percent recovery for a matrix spike must be at least 70%, while section B.(4)(vi) states that the desorption efficiency must be at least 75%. When adsorbent tube samplers are used, the "matrix spikes," at the NCEL, of section B.(4)(iv) and the desorption efficiency samples of section B.(4)(vi) are identical, therefore is the different criteria of 70% in Section B.(4)(iv) and 75% in section B.(4)(vi) intentional? The 70% criteria for the matrix spikes of section B.(4)(iv) that are at 0.5 the NCEL may be appropriate for allowing for the slight drop in desorption efficiency for smaller sampler loadings, which is sometimes typical.

6. Comment (SPI): One must be able to demonstrate that (1) the samples are quantitative, (2) repeatable, and (3) predictable. The first refers to the fact that sampling methods should recover a fixed amount or proportion of a known quantity of material under specified conditions. The second refers to the fact that under specified conditions, the method should recover the same quantity of material. The last indicates that one should be able to predict on the basis of observable facts what the correction factor should be. One hundred percent recovery is not only infeasible, it is scientifically unnecessary.

So long as one can be sure that, for example 50% of a material is recovered, simple arithmetic can compensate for the methodological inefficiency. This is what is meant by systematic bias in statistics and is of no concern with respect to the purpose of workplace monitoring--the assurance of protection of workers. Moreover, if we know that other factors will change sampling efficiency, such as humidity with many methods, we need only add that factor into our arithmetic to compensate for the imperfection

of human observation. The key is being able to relate what is in the air to what is happening to the worker.

EPA Response: EPA has added spiking levels to the method development criteria for matrix spikes and has followed NIOSH method development criteria. Direct spiking of the sampling cartridge or controlled atmosphere studies can provide this information. Matrix spikes using direct spiking followed by the passage of a certain volume of air or controlled atmosphere studies must meet a 75% to 125% recovery criteria. Desorption efficiencies are generally determined from direct spiking on the adsorbent tube. Desorption efficiencies must be 75% or greater. Precision requirements have been changed to incorporate the NIOSH/OSHA precision and accuracy targets. For example, accuracy has been defined as ± 25% with 95% confidence. This will eliminate the relative percent difference (RPD) issue. A precise method is desirable, but low recoveries (<60%) bring into question the actual adequacy of the method. EPA has allowed for the correction of recoveries within certain limits.

D. NCELs Quality Assurance Requirements

1. Comment (ETAD): Second, the quality assurance ("QA") requirements in the proposed NCELs program differ from, and are far more stringent than, current OSHA good laboratory practices ("GLP") requirements. There is no justification for imposing different and more stringent requirements on new chemicals than on existing chemicals. This is a particular concern of the dye industry, which is responsible for a significant number of PMN submissions and therefore would be affected to a greater extent than many other industries. EPA should follow the OSHA GLP requirements in its NCELs program.

2. Comment (SOCMA): The quality assurance ("QA") requirements contained in the proposed NCELs program differ from, and are far more stringent than, current OSHA good laboratory practices ("GLP") requirements. SOCMA submits that there is no material difference between workplace exposure to new chemicals and existing chemicals to justify EPA imposing different and more burdensome QA requirements. EPA should follow the OSHA GLP requirements in its NCELs program.

3. Comment (CMA): The burdens associated with method development will be magnified by the level of detail required in Part B of the proposed NCELs program ("Approval of Sampling and Analytical Method") and the inclusion of the OPPT Guidance Document for the Preparation of Quality Assurance Project Plans in the appendix. Stringent quality assurance requirements for sampling and analysis

in the new chemical program will not add to the quality of the data collected, but rather will unnecessarily increase costs.

4. Comment (CMA): In this regard, major changes in standard industrial hygiene practices would be necessary as a result of EPA's proposal to require the use of Good Laboratory Practice (GLP) requirements under TSCA, not only for analytical methods development but for the collection and analysis of workplace samples. No comparable requirements have been imposed under OSHA standards. OSHA regulations identify a level of quality control that must be met, not how that level of quality control is met. AIHA approves certain Industrial Hygiene laboratories that demonstrates they meet certain levels of quality assurance. While laboratories accredited by AIHA now have adequate quality assurance programs, they would not necessarily meet the stringent standards of EPA's GLP regulations. Monitoring the practices of certified laboratories to conform to the EPA requirements would be disruptive, costly and unnecessary, particularly in view of the absence of comparable GLP requirements in existing OSHA regulations establishing workplace limits.

5. Comment (SOCMA): The proposed NCELs program would impose very specific, burdensome and costly recordkeeping and reporting requirements on regulated parties. However, much of the same information could be obtained in a much less burdensome and costly manner through the use of existing laboratory standard operating procedures ("SOPs"). EPA should include a mechanism allowing the use of SOPs in lieu of NCELs procedures where comparable.

6. Comment (SPI): The quality assurance (QA)/quality control (QC) methods appear to mirror Superfund criteria. These may be acceptable for existing chemicals where QA methods have long been established and formalized but are not practical for new chemicals.

7. Comment (SPI): The QA requirements also go beyond current OSHA or EPA GLP requirements under other statutes administered by the Agency, e.g., FIFRA.

The NCEL approach as drafted will not alleviate the burdens posed by the existing 5(e) consent order process and may place new burdens on affected companies. Additionally, there may be a loophole in the NCEL approach if the production is halted at appropriate intervals levels.

8. Comment (SPI): Page 3, paragraph (d) - It is unclear whether this paragraph means both sampling and analytical must meet EPA GLP requirements. We would not expect EPA to review a sampling strategy before samples are collected. We anticipate EPA will only want the analytical and general sampling plan. The time and effort required to develop a new analytical method could be as much as 180

days for method development and validation (30-60 days with storage evaluation data, 30-60 days for internal review and approval and 15-60 days for collection of monitoring samples and analysis of these samples).

9. Comment (SPI): EPA GLPs are not necessary if the standard requires the documentation of accuracy and precision as noted above. Moreover, many of the requirements found in the GLPs are necessary for performing scientific studies where the purpose is to carefully control a limited number of independent variables. This is not the case in workplace air sampling and monitoring. Rather, here the objective is more akin to quality control sampling: the hypothesis to be tested is whether the exposures are above the limits. EPA should not be concerned how much below, or precisely how much above the NCEL exposures are, so long as the correct decision regarding protective equipment and the adequacy of the controls can be made. EPA should keep in mind that increases in scientific certainty come at a significant cost, and in some cases, such as this, the increased information adds nothing to the decision making process that is to be followed.

EPA Response: OSHA does not require GLPs. However, the American Industrial Hygiene Association (AIHA) Industrial Hygiene Laboratory Accreditation Program (IHLAP) was created in response to requests from OSHA and NIOSH to ensure the availability of labs providing reliable IH data to document compliance with OSHA PELs. The AIHA IHLAP has accredited over 300 labs.

TSCA GLPS are designed to specify minimum procedures to ensure accurate data. According to 40 CFR 792.1(c), "[i]t is the Agency's policy that all data developed under section 5 of TSCA should be in accordance with" TSCA GLPS. Therefore, EPA has retained the requirement for compliance with TSCA GLPS. However, EPA recognizes that routine IH monitoring is not the typical "study" for which TSCA GLPS are required, and that there are alternative ways to ensure accurate data. Therefore, EPA has revised this requirement to accept use of a laboratory accredited by the AIHA IHLAP, or another comparable program approved in advance in writing by EPA, as an alternative to compliance with TSCA GLPS.

EPA has also revised the NCELs provisions to clarify that: (1) the contents of the sampling and analytical method no longer must satisfy specified portions of the OTS Guidance Document for the Preparation of Quality Assurance Project Plans; (2) TSCA GLPS do not apply to NCELs method development ("The term 'study' does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility." 40 CFR 792.3), but do apply to method verification and

actual monitoring; and (3) certain provisions of the TSCA GLPS related to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCELs requirements.

E. Sampling Device Capacity

1. Comment (NIOSH): Sampling device capacity (page 18); in order to determine sampler capacity, the flow rate at which the analyte is collected should be specified, along with volume and mass of analyte. The humidity used for capacity determination should be appropriate to each analyte. In many instances, high relative humidity reduces the capacity of a sorbent for an analyte, but in some cases, low humidity may be more restrictive.

2. Comment (OSHA): Because it is possible to have a sampler whose capacity is enhanced by humidity, it may be appropriate to include a requirement in section B.(4)(v) which specifies that if humidity is determined to enhance sampler capacity, the capacity tests should be performed with dry air, which would be the worst-case condition. We currently have two methods development projects in progress, one for methanol and one for phthalic anhydride, in which we have found sampler capacity significantly enhanced by increased humidity.

3. Comment (SPI): A relative humidity of 80% may not be compatible with the properties of the substance being measured.

- Collection efficiency of the collection device needs to be taken into account.

- "You must take sample without any loss." That is totally infeasible, even with the most innovative sampling techniques.

4. Comment (SPI): Representativeness requirement may not be consistent with the humidity requirement on p. 18.

5. Comment (CMA): Page 18: The requirement that sampling devices must be capable of collecting samples without loss is impractical. Studies of three weeks in length are sufficient to determine any loss due to storage. Change "absorbent" to "adsorbent." For adsorbent tube monitoring, breakthrough should be defined as greater than 25% of the analyte detected in the backup section rather than 5% of upstream concentration. This standard is used by professional industrial hygienists and industrial hygiene laboratories. It is far easier to analyze a backup section of a

sampling tube or filter than to determine upstream headspace concentrations.

Must the sampling device capacity and desorption efficiency be determined in a controlled environment (generating a known vapor concentration), or can these factors be determined by drawing a known volume of air through a matrix spike? CMA believes this choice should be left to the discretion of the laboratory responsible for developing the method as long as appropriate documentation is available.

6. Comment (CMA): Page 19: Can either vapor-generated or matrix spikes be used to determine relative percent difference?

7. Comment (CMA): If less than a 30% difference is seen in percent recovery or in the sampling device capacity at low humidity (5-25%) and high humidity (75-95%), then the method should be deemed valid at any humidity level. (Corrections of up to 30% should be applied based on the data generated in the humidity studies.) If the difference between the results is more than 30%, then a mid-range (40-60%) relative humidity study is recommended. Corrections for humidity differences will be made based on the three data points generated.

Section (8) on representativeness is too restrictive. While different workplaces may have different environments, it is not necessary to test them all. A laboratory will review the method to avoid interferences. As long as high humidity is taken into consideration, other changes in the environment (i.e., lighting, presence of other chemicals) would not normally affect the method.

EPA Response: In instances where sampler capacity is enhanced by high humidity, the capacity determination should be conducted with dry air. In general, humidity requirements have been changed to be more practical, but the humidity used for capacity determination should be appropriate to each analyte. The NCELs language has been revised to be more consistent with NIOSH and OSHA. Methods using adsorbent tubes as the collection medium are allowed, provided evidence of the capacity is provided in the form of breakthrough testing. The efficiency of the collection device has been considered and addressed in the NCELs language. EPA encourages companies to include these types of details in their written description of the analytical method.

F. Fiber Structure

1. Comment (NIOSH): Page 21: "... the fiber chemical composition and nature..." This section should also include an additional requirement about the physical nature or structure of the fiber, specifically how does the fiber behave (does it split

longitudinally into additional fibers or smaller diameters?). Also, the surface properties of the fiber are important and may not be included in the term "chemical composition and nature."

2. Comment (Labor): Item 10 on Fibers (pp 21-22) fails to address the respirability of fibers. Since the NCEL focus rests on inhalation exposures, and presumably hazards/health effects resulting from inhalation, an NCELs for a fiber must be based on a TWA for fiber sizes which are respirable. Thus, the sampling and analytical methods developed or used must define what is a respirable fiber (i.e., fiber diameter and aspect ratio) for establishing an NCEL.

3. Comment (Labor): If the characterization of fiber size distribution performed on both bulk fiber and on air samples collected in the workplace (as called for in this draft) establish that no respirable fibers are present, then an NCEL for total dust should be developed.

4. Comment (CMA): Page 21: Transmission electron microscopy should not be required for fiber analysis. Analysis by light microscopy is sufficient.

5. Comment (SPI): "Fibers" needs to be defined. There should be threshold parameters for this definition.

EPA Response: EPA has deleted the paragraph pertaining to fibers.

G. Continuing Calibration

1. Comment (NIOSH): Instrument calibration (page 17): Weekly calibration of a method is too infrequent. NIOSH calibration standards are typically intermixed with samples to account for minimal instrument variation during analysis. The method is then calibrated after the analyses are completed. For the "initial" calibration curve, the lowest chemical standard should be below the NQL, not at the NQL. In fact, a chemical standard should not be at or below the LOD concentration.

2. Comment (CMA): Page 17: What does the term "continuing calibration sample" mean in this context? Does it refer to a standard that is used from one week to the next, to a new standard made up each week that samples are compared to, or is some other meaning intended?

EPA Response: Calibration must be conducted before analyses and every tenth sample during analysis. These calibrations are

conducted to assess instrument stability. A calibration sample refers to a standard close to the NCEL, which is run with every batch of samples and used to establish a time limit associated with the stability of the standards.

H. Definitions

1. Comment (NIOSH): Limit of detection (LOD) (page 16): ACS or NIOSH definitions should be considered. We have enclosed recently finalized NIOSH standard operating procedures for industrial hygiene sampling and chemical analysis that include NIOSH definitions for LOD and LOQ.

2. Comment (SPI): The duplicate sample definitions needs to be clarified.

EPA Response: EPA has made these definition consistent with NIOSH and the American Chemical Society (ACS).

I. NCEL below LOD

1. Comment (CMA): If the development of the analytical method indicates that the NCEL is below the limit of detection, a mechanism must be available for companies to meet with EPA and negotiate a change in the proposed limit.

EPA Response: The NCELs option will not be possible if the method cannot reliably measure the action level. A re-evaluation of the NCEL may be possible based on the health risks and technological feasibility, but an upward adjustment of the NCEL cannot be guaranteed.

J. Sampling Intervals

1. Comment: NCEL Flow Chart - The requirement that periodic monitoring should be continued until two samples, not less than seven days apart, are below the action level is unscientific. A more correct approach is to require that the samples be representative of the exposure of the workers who are being protected. The question is one of selecting an unbiased sample to reflect accurately the exposure being monitored, and an arbitrary seven day period between samples is no more scientific than any other arbitrary period. Selecting an unbiased sample period is not a question of proximity in time, but of being able to support the conclusion that the data are accurate by observations showing that the selection of the sample period was unbiased.

It is equally likely that for most processes under the right circumstances, two samples collected on consecutive days may be more representative of the worker's total exposure than two samples taken seven days or more apart. EPA should not specify a time period, but should require only that there be some objective evidence that the samples collected are representative.

2. Comment: Page 25: The requirement in Section (3) for taking measurements at least seven days apart should be revised. Samples should be taken when an operation is running and when the opportunity for exposure is high, rather than at a set interval of seven days.

EPA Response: The flow chart has been deleted. EPA's revisions to the NCELs provisions reduce the monitoring requirement for "Reductions in Respiratory Protection" and "Terminations of Periodic Monitoring" from two consecutive measurements at least 7 days apart (as required by OSHA) to two consecutive measurements at least 24 hours apart for batch production processes of durations less than 7 days, provided that these measurements accurately reflect the highest peak exposures and variability in exposure.

K. Changes Affecting Validity of the Method

1. Comment (SPI): Page 20 (9) - "Changes affecting validity" are difficult to manage and enforce. This requirement needs further clarification.

2. Comment (CMA): A further disincentive to using the NCELs process is the proposed requirement to revalidate sampling and analytical methods where "changes in the workplace environment" could affect the validity of those methods. As proposed, this open-ended approach could require revalidation, with all the attendant effort and expense, in situations where changes in the workplace are unlikely to affect a method's validity. A better approach is to require revalidation only where there is strong evidence to suspect that a workplace change will in fact impair the method's validity--i.e., when a new compound introduced to the workplace environment is known to interfere with detection of the PMN substance.

EPA Response: EPA agrees and has amended the language to place the responsibility upon industry to revalidate the method when changes in the workplace are reasonably likely to invalidate the accuracy of the sampling and analytical method.

L. Other Sampling Methods

1. Comment (NIOSH): Approval of sampling and analytical methods (page 15): section should include reference to interferents that may influence the analytical outcome. The section is oriented to solid sorbent media collection. Other collection media should be addressed as well.

2. Comment (SPI): The NCEL language should be more generically written so that a company would have more latitude in determining the type and quantity of air monitoring to be accomplished.

EPA Response: The section in question has been revised to be less focused on any one particular methodology and more inclusive of other available sampling methodologies.

M. Measurement Properties

1. Comment (NIOSH): Contents of submission (page 15): The text should refer to "chemical and physical properties" of the given substance rather than "Properties pertinent to its measurement."

EPA Response: The "contents of submission" provision has been deleted.

V. MONITORING REQUIREMENTS

1. Comment (SPI): NCEL Flow Chart - The requirement that periodic monitoring should be continued until two samples, not less than seven days apart, are below the action levels is unscientific. A more correct approach is to require that the samples be representative of the exposure of the workers who are being protected. The question is one of selecting an unbiased sample to reflect accurately the exposure being monitored, and an arbitrary seven day period between samples is no more scientific than any other arbitrary period. Selecting an unbiased sample period is not a question of proximity in time, but of being able to support the conclusion that the data are accurate by observations showing that the selection of the sample period was unbiased.

It is equally likely that for most processes under the right circumstances, two samples collected on consecutive days may be more representative of the worker's total exposure than two samples taken seven days or more apart. EPA should not specify a time period, but should require only that there be some objective evidence that the samples collected are representative.

2. Comment (CMA): Page 25: The requirement in Section (3) for taking measurements at least seven days apart should be revised.

Samples should be taken when an operation is running and when the opportunity for exposure is high, rather than at a set interval of seven days.

EPA Response: EPA's revisions to the NCELs provisions reduce the monitoring requirement for "Reductions in Respiratory Protection" and "Termination of Periodic Monitoring" from 2 consecutive measurements at least 7 days apart (as required by OSHA), to 2 consecutive measurements at least **24 hours** apart for batch production processes of durations less than 7 days, provided that these measurements accurately reflect the highest peak exposures and variability in exposure.

3. Comment (SOCMA): The NCELs Flow chart indicates that periodic monitoring is required at least every 6 months if two consecutive measurements below the acceptable limit at least 7 days apart cannot be obtained. This suggests that if the initial measurement exceeds the acceptable limit, workers would be required to wear respirators for 7 days pending the second measurement. EPA should provide an employer with the option of taking a second measurement immediately upon receipt of the result of the first to determine whether the initial reading was due to an analytical error, an unusual circumstance, or was a "true" reading of workplace exposure.

4. Comment (CMA): The monitoring requirements are numerous, variable, and often vague. The immense effort to achieve compliance, in addition to the considerable requirements for recordkeeping, is not conducive to industry adoption. For example, if a chemical is detected at a concentration that is over the "acceptable limit," does the company collect two samples, 7 days apart? If so, what protection is required for workers between these sampling events, i.e., must respirators be worn for 7 days? CMA believes that immediate remeasurement following detection of an unacceptable concentration should be allowed in the proposed requirement to determine if the initial result represented a "blip" (such as a process upset) or is indicative of normal operations.

The periodic monitoring requirements are not sufficiently flexible for companies who use batch processes. In addition, monitoring in the event of a spill is unrealistic--it would be preferable to have protected personnel clean up the spill immediately, rather than wait until the monitoring team arrives to take samples.

EPA Response: The flow chart was intended to help illustrate the relations between the various NCELs provisions. It has been deleted.

The NCELs requirements were derived from OSHA existing requirements, with modifications made where appropriate. The "2 consecutive measurements taken seven days apart" language was copied from OSHA comprehensive standards. If a company wants to decrease the monitoring or respirator requirements after a chemical is detected at a concentration that is over the NCEL, the company would need to collect two samples, seven days apart. In this event, appropriate personal protective equipment, including respirators, would have to be worn during the intervening seven days if workers would otherwise be exposed to the PMN substance.

The language is sufficiently flexible for batch processes as it only requires monitoring in the event the substance is actually being manufactured, processed, or used during a specified monitoring period. Additionally, EPA's revisions to the NCELs provisions reduce the monitoring requirement for "Reductions in Respiratory Protection" and "Termination of Periodic Monitoring" from 2 consecutive measurements at least **7 days** apart (as required by OSHA), to 2 consecutive measurements at least **24 hours** apart for batch production processes of durations less than 7 days, provided that these measurements accurately reflect the highest peak exposures and variability in exposure.

The NCELs language applicable to spills has been modified to enable appropriate clean-up efforts to take place, with workers wearing appropriate personal protective equipment before, or in conjunction with monitoring.

5. Comment (Labor): In general, we endorse the proposed "New Chemical Exposure Limits" section as an alternative to be used to address inhalation hazards. This can represent a major step forward for worker protection owing to the inherent questionable reliability of respiratory protection programs. However, the very nature of a "new chemical substance" infers a certain lack of knowledge regarding human exposure health consequences both acute and more troubling, chronic, which places an added burden on both EPA and the employer with regard to worker protection. In that regard, the NCEL approach must be based upon this recognition. Considering this, the proposed periodic monitoring requirement of every 6 months unless E(5) [now (d)(5)] is triggered, is seriously deficient. Further, additional monitoring "within 7 days" if E(5) is triggered is likewise deficient. A substantial change in the monitoring requirements is needed. Periodic monitoring should also be based upon or keyed to the Action Level.

EPA Response: The monitoring requirements were developed based on existing monitoring requirements in OSHA standards, such as for benzene (29 CFR 1910.1028). The periodic monitoring requirements for OSHA standards vary from no requirements (29 CFR 1910.1000) to

monthly, quarterly, every 6 months, or annually. For example, OSHA's benzene standard requires periodic monitoring at least every six months, triggered by measurements above the TWA, but only annually for measurements between the TWA and the action level. EPA, in the NCELs language, has strived to maintain consistency with the OSHA requirements, as appropriate. EPA considers 6 months to be a reasonable period of time in which to take such measurements when prior monitoring did not exceed the NCEL, and represents an average or median value among the differing OSHA monitoring requirements. However, where prior monitoring exceeds the NCEL, EPA has revised the NCELs provisions to require periodic monitoring every 3 months.

EPA has modified the language to address the comment regarding "within 7 days" to clarify that monitoring shall take place within 7 days of: (1) a change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substance, (2) spills, leaks, ruptures or other breakdowns which occur that may reasonably cause new or additional exposures to the PMN substance, or (3) when the company has any reason to believe or suspect a change that may reasonably result in new or additional exposures to the PMN substance. Additional language makes clear that in no event is the additional monitoring requirement in subparagraph (d)(5)(a) intended to delay implementation of any necessary cleanup or other remedial action. During any such operations that may occur before commencing additional monitoring, the company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (d) based on the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a technically qualified expert. The modifications are more consistent with existing OSHA standards.

6. Comment (SPI): The NCELs language should be more generically written so that a company would have more latitude in determining the type and quantity of air monitoring to be accomplished.

EPA Response: The requirements are consistent with current OSHA requirements. There is sufficient latitude within the requirements to accommodate changes in production. If the OSHA requirements for monitoring are revised, EPA will re-evaluate the NCELs requirements. EPA is also aware that OSHA is currently developing a Generic Exposure Monitoring Standard which, if appropriate, could be adopted by EPA.

NOTE: Supplemental comments were submitted by CMA in March 1993 (not included verbatim here) the primary gist of which was to urge that EPA should allow statistical approaches to analyses of monitoring results. Again, this would go beyond current OSHA

requirements, and EPA will generally defer to OSHA's lead in developing policy on regulating workplace exposures. EPA may explore the subject further if resources become available.

7. Comment (SPI): There may be a loophole in the NCEL approach if the production is halted at appropriate interval levels.

EPA Response: The NCELs language does not require monitoring if the substance is not manufactured, processed or used during a given 6-month calendar period.

8. Comment (SPI): Given the potential overlap with OSHA, we urge EPA to defer to OSHA regarding the air monitoring and workplace control aspects discussed in the draft order.

EPA Response: EPA is required by law to administer Section 5 of TSCA, and to the extent that the Agency's mandate is to prevent, among other things, unreasonable risk to human health, it is well within EPA's purview to impose requirements to effect risk reduction which may occasionally overlap with OSHA requirements. The NCELs general monitoring requirements are based on existing OSHA requirements for protecting workers from airborne exposure to chemicals and are consistent with OSHA regulations designed for that very purpose. EPA will consider changes made to OSHA monitoring and workplace control requirements in the NCELs program.

9. Comment (NIOSH): Should include provision for exposure regimes of more than 8 hours duration.

10. Comment (SPI): Page 22 - It is unclear in the draft how a company would handle workshifts of more than 8 hours. One may have to ratio down the TWA or leave it the same.

Page 22-c(1) - Where increased workshift schedules exist, an 8 hour-TWA will not be adequate.

Page 27 - 8 hour-TWA - Alternative workshifts need to be considered here too.

EPA Response: EPA has elected to establish New Chemical Exposure Limits based on the conventional 8-hour day, 40 hour work week, as is commonly done for exposure limits set by the ACGIH and OSHA. However, EPA recognizes that other work regimes may exist and protection provided should be equivalent to that provided to workers with conventional schedules. There is guidance presented in both the ACGIH TLV Handbook and in Patty's Industrial Hygiene and Toxicology (standard industrial hygiene reference texts). EPA suggests that these references or other equivalent references be consulted to address this issue. These approaches reduce the

exposure limit proportionally for increased exposure time, and for reduced recovery (non-exposure) time.

11. Comment (SPI): The period should be defined to determine changes in production volume.

EPA Response: The requirements for periods of measurement were based on existing OSHA requirements, with minor modifications made as necessary to allow flexibility for small volume, batch operations. The language has been clarified to reflect the OSHA language on monitoring. This will clarify the sampling requirements and help in maintaining consistency with applicable OSHA requirements. The language addressing spills has been modified to be more consistent with existing OSHA requirements. The language is sufficiently flexible for batch processes as it only requires monitoring if the substance is actually being manufactured, processed, or used.

12. Comment (Labor): Periodic monitoring should also be based upon or keyed to the Action Level.

EPA Response: Monitoring is keyed to both the action level and the time weighted average (TWA).

13. Comment (SPI): "Exposure" can't be sampled, the concentration in air can. A value less than the detection limit should not be equated to the limit for the purposes of this order.

EPA Response: Section (d)(1)(ii) of the NCELs provisions states that "...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."

VI. RESPIRATORY PROTECTION

1. Comment (NIOSH): The selection of appropriate respiratory protection in the absence of data on toxicity and "immediately dangerous to life and health" (IDLH) characteristics would suggest that positive pressure respirators would be the minimum starting point for respirator selection [NIOSH 1987].

EPA Response: EPA does consider potential health effects and toxicity when selecting respiratory protection. The procedures used for selecting respirators are based on NIOSH recommendations in the "Strategy for Recommending Respirators for Control of Exposures to Substances Undergoing Premanufacture (PMN) Review" and

the NIOSH Respirator Decision Logic (1987). Where appropriate, EPA will allow use of respirators which are not positive pressure for new chemical substances. This determination is based on information provided in the PMN, methodologies used by EPA for evaluating potential human health effects and occupational exposure, and experience gained in reviewing over 20,000 PMNs. Due to a lack of toxicity and exposure data on the substance, EPA assessments tend to err on the conservative (i.e., protective) side, such that potential exposures and hazards are generally over-estimated. If, based on these conservative estimates, a positive pressure device is not needed, EPA will allow the use of negative pressure devices.

EPA generally does not have the information to determine IDLH exposure conditions for PMN substances, and requires the PMN submitter to select the appropriate NIOSH-approved respirator in accordance with 29 CFR 1910.134, the Respiratory Protection standard. Concern due to acute health effects is very rare in the New Chemicals Program. In fact, of the about ten '5(e) Orders issued to date containing NCELs provisions, all have been concerned exclusively with chronic effects and none have included a short term exposure limit (STEL).

2. Comment (SPI): Page 24-25- The measured concentrations appear without justification.

EPA Response: These concentrations were developed based on the NIOSH Assigned Protection Factors as given in the NIOSH Respirator Decision Logic, 1987. The NIOSH Assigned Protection Factor is defined as "the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users" (NIOSH, 1987).

3. Comment (Labor): Tables, page 33-37: There is no difference in the need to know cartridge performance data between an "organic vapor" cartridge (page 36) and a "paint spray" cartridge (page 33). Why is the "Paint Spray Mist Exposure" table not headed by a requirement for performances data submission and approval by EPA? All the respirators listed on the page 35 table are SARs. They have no cartridges. Why the requirement for submission of cartridge data?

These tables could be replaced with the NIOSH Revised RDL Tables.

EPA Response: The requirement for cartridge testing is determined on a case-by-case basis. In general, most PMN substances used in paint spray applications occur in the particulate or mist form, rather than in vapor form, and organic vapor cartridge testing is not needed for the particulate form. With substances for which EPA

is concerned about vapor exposure and the company wishes to select an air-purifying respirator, cartridge testing would be required.

VII. RECORDKEEPING

1. Comment (CMA): Adding to monitoring burdens is the requirement that companies discontinue monitoring for a particular exposure group and prepare an annual report documenting the absence of workplace changes (that could result in increases in exposure). No comparable requirement is imposed under OSHA standards. Here again, consistency with the OSHA approach will eliminate unnecessary burdens. The purpose of discontinuing periodic monitoring where exposures are below the action level is to minimize compliance burdens in workplaces that pose low risks to employees. This purpose would be largely nullified if such workplaces are subject to continual reporting and recordkeeping requirements that assure exposure levels remain low.

EPA Response: EPA acknowledges that the requirement that companies submit an annual report following termination of monitoring does go beyond what OSHA currently requires. Therefore, with an eye towards streamlining NCELs to establish a closer alignment with OSHA PELs, and hence increase its acceptance by the regulated community, EPA has chosen to delete this requirement.

2. Comment (CMA): The recordkeeping requirements included in EPA's proposed consent order are also more elaborate than the comparable provisions of OSHA standards. While full records of workplace monitoring should be retained, EPA's proposed consent order would require additional documentation that could be quite extensive. Companies must retain records of "any condition that might have affected the monitoring results" and of "any actions taken to mitigate exposures to the PMN substance." Records documenting "any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure" must also be retained. These requirements, in CMA's judgment, are excessive and should be streamlined so they parallel the comparable provisions of OSHA standards.

3. Comment (SPI): The NCEL proposal will present compliance difficulties, especially with respect to much detailed recordkeeping and reporting. The guidance document provides several good suggestions but carrying out all the requirements will put undue and unnecessary burden on those subject to 5(e) Orders as well as add substantial costs which may prohibit market entry of new chemicals.

EPA Response: EPA has attempted to keep the NCELs recordkeeping requirements to a minimum necessary for viable compliance monitoring and enforcement. For example, to document that workers are in fact being adequately protected, it is essential to keep records of monitoring results, as well as grounds for termination or resumption of monitoring. In general, the recordkeeping requirements comport with good business practice and would be required to be maintained under the Occupational and Safety Health Act and regulations as well as by some private insurers.

4. Comment (CMA): Page 30, 58: Because of the proprietary nature of the information requested here, EPA must be prepared to either keep this confidential, or allow companies to maintain records in-house and make them available upon request for inspection.

EPA Response: The language in the recordkeeping section of the NCELs portion of the Consent Order is clear that records are in fact to be maintained in-house by the company, and made available to EPA upon request for inspection. The company is not otherwise required to submit these records to EPA.

5. Comment (Labor): This section should be modified to: (a) Note that even when using a "new chemical" an employer is still responsible for providing a safe and healthful work environment per the OSHA regulations; (b) The OSHA Recordkeeping requirements, and access thereto, are governed by 29 CFR 1910.20. The 5 year recordkeeping requirement noted, for example, violates 1910.20.

EPA Response: Since existing OSHA regulations already require these employee exposure records to be kept for 30 years, EPA will do likewise. Title 29 CFR 1910.20(d)(ii) requires employers to keep employee exposure records for 30 years for employees exposed to "toxic substances or harmful physical agents." 29 CFR 1910.20(b)(1). "Toxic substances or harmful physical agents" are defined at 1910.20(c)(13) to include any chemical substance which: (i) Is listed in the NIOSH Registry of Toxic Effects of Chemical Substances (RTECS); (ii) Has yielded positive evidence of an acute or chronic health hazard in testing; or (iii) Is the subject of a material safety data sheet (MSDS) indicating that the material may pose a hazard to human health. Since all NCELs '5(e) Orders require an MSDS indicating a potential health hazard, the 30 year recordkeeping requirement under 29 CFR 1910.20 will automatically apply to the PMN substance.

Since OSHA and EPA may both have jurisdiction simultaneously, the company would still be required to comply with OSHA's 30 year requirement, even if EPA only imposed a 5 year requirement. Since the company is therefore required by OSHA to keep these records for 30 years, EPA has decided to revise its NCELs recordkeeping

requirement to harmonize it with OSHA and require the company to keep NCELs exposure records for 30 years.

VI. MISCELLANEOUS

1. Comment (SPI): The NCEL approach as drafted will not alleviate the burdens posed by the existing 5(e) Consent Order process and may place new burdens on affected companies.

2. Comment (CMA): CMA supports the concept of NCELS but believes its implementation should be streamlined. As proposed, the NCELs concept could cause lengthy delays in the finalization of the Section 5(e) Orders and place unreasonable administrative burdens on manufacturers.

EPA Response: Largely in response to comments received by outside parties, EPA has revised the NCELs program to make it less burdensome on industry while still providing adequate protection to workers. Such changes include, among other things, modification of analytical requirements, allowance of reliance on objective data, and deletion of the requirement that companies prepare an annual report after monitoring is terminated.

3. Comment (SOCMA): SOCMA would appreciate an opportunity to meet with you at your convenience to discuss in more detail the technical and procedural issues outlined in these comments.

EPA Response: The need for such a meeting may be obviated by the revisions EPA has made to the NCELs program. Should this not be the case, EPA welcomes the opportunity to meet with interested parties.

4. Comment (SOCMA): The regulated community should be provided an opportunity to review and comment on the revised program prior to its adoption.

EPA Response: The NCELs requirements have undergone a lengthy review process. EPA believes that all interests are best served by EPA implementing the revised NCELs program immediately, without further delay. Unlike rulemaking activity, however, development of '5(e) Consent Orders contemplates an evolving case-specific approach. If necessary, the specific terms of individual '5(e) Orders may be negotiated so that their terms are more appropriately tailored to the specific facts of an individual PMN case. Additional information which is brought to the Agency's attention by the submitter is always considered. Upfront submission of comprehensive information in the PMN submitter's possession and

control will therefore greatly enhance the precision of the Agency's risk assessment and ensuing regulatory controls.

5. Comment (Labor): Action Level: E(1)(i) does not define the action level. Is it 50% of the NCEL or different for each new chemical based upon EPA's review?

EPA Response: The "action level" is always half the NCEL. The generic '5(e) Order language has been revised to reflect this.

6. Comment (SPI): There are some flaws in the flow chart:
(a) there is always the possibility of a process change or breakdown.
(b) the loop for (a) above after the "release to air =no", if process change results in a release to air, it is not clear how the loop is affected.
(c) there appears to be an endless loop at "Notify Affected Persons.."

7. Comment (SPI): The flow chart contains a box "EPA Approved Analytical Method." The only way you can get out of the box is to develop an approved method. Thus, the title should reflect what is actually required to be done.

EPA Response: The flow chart was intended merely to provide a simplified illustration, and not to substitute for the requirements specified in the 5(e) consent order. However, to avoid confusion, the flow chart has been deleted.

8. Comment (Labor): Medical Exams and Surveillance: A section on medical exams and surveillance should be included:
a. To determine whether workers are medically capable of wearing respirators.
b. Monitor any resulting health effects of exposure to a PMN substance for which not much is known about its toxicological properties. Exams could be designed based upon the toxicological properties of other chemicals that have similar molecular structures.
c. Will act as a check on the adequacy of PPE, including respirators.
d. Will act as a check on the adequacy of the NCEL for a given PMN substance.

The Medical Exam and Surveillance requirements must comply with the Recordkeeping requirements of OSHA standards under 29 CFR 1910.20 as well.

EPA Response: 29 CFR 1910.134 requires a medical exam for respirator selection and is required by reference in the '5(e)

Order. However, EPA does not plan to address this issue at the current time. Suggestions, comments or documents bearing on medical exams and surveillance are, of course, welcomed by the Agency. EPA is aware of OSHA's effort to establish generic medical surveillance requirements, and EPA may revisit this issue when the OSHA requirements are finalized.

9. Comment (Labor): Labeling should include physical (safety) hazards under (i)(A).

MSDS should include (xiii), the NCEL AL and STEL specified by EPA. In addition, the OSHA HAZCOM standard (1910.1200) language regarding access to claimed confidential information by various parties in both emergency and non-emergency situations should be used.

Training under (2)(ii) should include physical hazards. Subsection (g)(1) through (4) should be modified after OSHA's 20 CFR 1910.1200 appendix A and should include physical hazards.

EPA Response: EPA agrees that the MSDS should include the NCEL and STEL, and has now included them in the Hazard Communication requirements in the Consent Order. Although, EPA's New Chemicals Program does not specifically address physical hazards, EPA encourages companies, in keeping with the spirit of hazard communication, to include warnings of physical hazards.

10. Comment (CMA): Do these sections imply that the selection of protective equipment cannot be based on data from similar chemicals but must be based solely on the new chemical? CMA believes that relevant information on similar chemicals can be used to make decisions about worker protection.

11. Comment (SPI): It appears that one cannot select protective equipment based on analogous data to a similar chemical but must test each PMN chemical separately. This could represent a significant burden for a company and does not recognize well-established practice.

EPA Response: As a general rule in the NCELs program, EPA expects that selection of appropriate respiratory protection for the PMN substance will be based on monitoring of the PMN substance itself. On a case-by-case basis, EPA will consider, and has allowed, use of analogue data for monitoring exposures to the PMN substance and selecting appropriate personal protective equipment. To rely on monitoring of an analogous substance, the company must adequately demonstrate to EPA the validity of its proposed approach, for example, that the quantitative ratio between the analogue substance and the PMN substance will be constant, so that the analogue substance provides an accurate measure of the PMN substance. EPA

routinely accepts information provided by submitting companies in its deliberations.

VII. NON-NCELs

1. Comment (AIHA): Greater reliance on industrial hygiene professionals should be reflected in TSCA Section 5(e), not just in the proposed NCEL section but in all aspects of worker protection. Reference to industrial hygienists for worker protection and other aspects under TSCA would improve compliance with worker protection directives.

The worker protection and NCEL sections currently proposed, under TSCA Section 5(e), were considered by some AIHA reviewers to be confining and (depending on the situation) unnecessary. If the professional judgment of industrial hygienists is relied upon, some of the micromanaging detail that would cost both the agency and industry time and effort could be avoided.

AIHA suggests that beginning on the bottom of Page 8, Protection in the Workplace under TSCA Section 5(e), EPA should include reference to industrial hygienists to allow changes to be made in the worker protection plan as appropriate. This modification will allow necessary flexibility to be exercised professionally by industrial hygienists for changing workplace protective measures with no compromise to worker safety and health.

EPA Response: EPA recognizes the capabilities of the industrial hygiene (IH) profession, and encourages all Industrial Hygienists to participate actively in issues bearing on new chemical substances, such as the NCELs program. The worker protection requirements are based on existing OSHA and NIOSH requirements, as well as good industrial hygiene practice, with the intent of providing consistency for those facilities which must meet both EPA and OSHA monitoring requirements. If changes to the consent order requirements are necessary in an individual case, these can be negotiated before the order is signed, or revised afterwards by petitioning the Agency to modify the terms of the order. If OSHA monitoring requirements are modified, EPA will reevaluate these requirements, as appropriate.

2. Comment (ACTWU): Effectiveness of respirator program rules: The respirator requirements are inadequate in that they do not provide for mandatory monitoring of exposures. It is inconceivable to us how an employer can design a truly protective respirator program without having first characterized the extent of workers' exposure.

There are other problems as well with the requirements for this program. Prominent among these is the absence of any consideration for the health effects of respirator use on the

workers in question, especially on workers exposed to respiratory toxins. In view of the failure of this program's requirements to adequately complement the typical exposure monitoring and medical surveillance rules in OSHA health standards, I suggest that you reconsider the entire structure of the proposed Consent Decree. In particular, I suggest that you gather detailed data from some or all of 600 situations where EPA has already signed consent decrees to determine the extent to which workers have suffered adverse health effects. In doing so, you should involve NIOSH due to EPA's inability to clinically evaluate the health status of active workers.

EPA Response: EPA's respirator requirements in the Protection in the Workplace section of the Order incorporate by reference the OSHA respirator requirements under 29 CFR 1910.134. While 29 CFR 1910.134 does not explicitly require monitoring for respirator selection, good industrial hygiene practice would dictate development of an exposure assessment based at least on consideration of relevant objective data, if not actual monitoring. Medical surveillance requirements are also contained in 1910.134.

More importantly, the above comment directly underscores much of EPA's underlying rationale for developing the NCELs program. EPA is fully aware of the potential problems associated with respirator use and is proposing the NCEL approach as an alternative to respirator use. Source reduction, engineering and administrative controls are preferred by EPA to the use of respirators.

The suggestion about collecting data on adverse effects to workers from substances regulated by '5(e) Orders is a good one. However, most data of this type should be reported pursuant to '8(e) of TSCA. Although current resource constraints prevent the Agency from being able to do more at this time, EPA may consider such a study in the future.

3. Comment (Labor): Protection in the Workplace Section: The a(1) references to 29 CFR 1910.132 and 1910.133 as PPE selection and use requirements would be usefully improved if 29 CFR 1910.120(g) and appendix D were added. 1910.120 addresses PPE requirements, particularly where exposures may be unknown, in far better fashion than does 1910.132 and 133. Further, 1910.120 is often not familiar to most employers so reference therefore would highlight this superior approach to PPE.

Subsection a(4) might usefully reference the Revised NIOSH Respirator Decision Logic (NIOSH Publication No. 87-108, May 8, 1987) as one basis for the required respiratory protection program. In addition, a(4) might be revised to state that the NIOSH RDL serves as the basis for respiratory selection. 30 CFR 11 serves as the basis for respirator certification and that only respirators

certified pursuant thereto may be utilized, and that 29 CFR 1910.134 serves as the minimum requirements for respirator use. It is useful to note that 1910.134 requires a medical exam per our suggestions for a medical exam and surveillance program.

EPA Response: OSHA has revised the personal protective equipment (PPE) requirements for face, head, eye and foot protection to reflect improved developments and allow the use of better personal protective equipment. These improved requirements are incorporated by reference in the NCELs provisions of the '5(e) Consent Order. However, the requirements of 1910.120 address PPE selection for hazardous waste and emergency response which are inappropriate for many industrial operations regulated by TSCA '5. EPA requirements are consistent with comparable OSHA requirements. EPA may impose additional requirements for upfront glove permeation testing or other requirements in cases where EPA is especially concerned about dermal exposure to a particular PMN substance.

4. Comment (CMA): Does EPA have a mechanism for updating the 5(e) order if the specific ASTM methods cited on page 10 of the draft are revised or superseded? CMA suggests that a statement be provided in this section that refers to the use of "the best available method."

EPA Response: EPA has mechanisms for updating the 5(e) Order requirements as the ASTM methods are revised and superseded. Where there is a recommended method, EPA would prefer to use the most current and recommended method for PMNs, and to keep abreast of these changes.

5. Comment (SOCMA): Regarding page (vi) of the preamble of the draft Section 5(e) Order, EPA should explain how it plans to estimate dermal exposure and inhalation exposure for the purpose of establishing NCELs.

EPA Response: Methods for estimating occupational dermal and inhalation exposure are explained in the Chemical Engineering Branch (CEB) Manual used by EPA/OPPT's CEB. The CEB Engineering Manual has been provided to many industry contacts and is available from CEB upon request. It is unnecessary to include this level of detail in the preamble of each consent order. To request a copy, please call the CEB at (202) 260-1664.

6. Comment (NIOSH): Several reviewers were concerned that potential toxic effects from dermal exposures were not adequately addressed. The exemption for solutions of less than 1% concentration may not be appropriate for toxic substances with low

saturation concentrations [Brown et al. 1984; Kissel and McAvoy 1989].

EPA Response: The standard 1%/0.1% de minimis exemption provision is deleted by EPA in cases where it is inappropriate. Cases are individually analyzed to ensure that all the provisions in the Order are tailored to the specific chemical substance under review.

7. Comment (Labor): Acute Illness: EPA should require that any acute illness suffered by a worker caused or potentially caused by the "new chemical" be documented and reported to EPA.

EPA Response: If the "new" chemical is implicated as the cause of serious adverse effects such as those listed in Part V(a) of EPA's March 16, 1978 TSCA Section 8(e) Policy Statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk"; 43 FR 11110, March 16, 1978, as amended at 52 FR 20083, May 29, 1987), such information must be reported immediately to EPA under Section 8(e) of TSCA. Further information regarding Section 8(e) reporting can be obtained from EPA's TSCA Hotline at (202) 554-1404.

8. Comment (Labor): New Chemical Ingestion: The oral exposure route is essentially ignored. It should not be. Requirements addressing prevention of oral exposure, where appropriate to the specific new chemical, should be included in the "Order."

EPA Response: EPA does consider potential hazards from ingestion due to oral exposure. There are no specific requirements for preventing oral exposure as many work places using new chemicals are also regulated by OSHA and would be subject to existing OSHA Standards which address prevention of oral exposure. Specifically, 29 CFR 1910.141, which applies to "permanent places of employment", requires that no employee is to consume food or beverage in any area exposed to a toxic material. In addition, this section imposes other general environmental controls. To the extent that these OSHA provisions apply to any signatory of the '5(e) Order, additional constraints are not necessary to prevent oral exposure to the new chemical substance.

9. Comment (SPI): Page 38 - It is confusing what specifically is covered by HAZcom and what is not. The NCEL requirements appear to be over and above HAZcom requirements and need to be clearly defined. Clarification is also needed as to how changes in HAZcom will affect NCEL requirements. There does not seem to be any relief here for future HAZcom actions that may duplicate or replace the EPA mandated actions.

EPA Response: The NCELs and Hazard Communication requirements are very different in nature. EPA has essentially adopted the provisions of OSHA's Hazard Communication Standard (29 CFR 1900.1200) in '5(e) Consent Orders where the PMN substance may present an unreasonable risk of injury to human health. These provisions govern the manner in which the hazards which are related to the PMN substance are to be communicated to persons reasonably likely to be exposed to the PMN substance. The NCELs provisions provide companies with an alternative to respirator protection only and do not preempt the provisions of the Hazard Communication Program section of the order. The provisions in the Hazard Communication section do not address respirator use, and would therefore not pose any conflicts with the NCELs provisions.

10. Comment (SPI): Page 42- All chemicals do not have both chemical and common names.

Page 17- Human health hazard statements do not address possible eye effects.

EPA Response: All chemicals have chemical names. If a chemical has no common name, none would be required. Eye effects are relatively uncommon. However, if EPA has a concern that a particular substance may cause eye effects, EPA would add such a statement in the individual '5(e) Order for that chemical substance.

Attachments:

I. Description of EPA's NCELs Standard Setting Methodology
II. List of References
III. EPA's Aug. 6, 1991 Draft of NCELs TSCA '5(e) Order

ATTACHMENT I

EPA'S METHODOLOGY FOR DETERMINING AN APPROPRIATE NEW CHEMICAL EXPOSURE LIMIT UNDER '5(e) OF THE TOXIC SUBSTANCES CONTROL ACT

There are usually no direct toxicity data on a new chemical on which to base an exposure limit. However, EPA may determine that toxicity data on one or more structurally analogous existing chemicals supports a finding that a new chemical may present an unreasonable risk of injury via inhalation exposure. Because such analogue may provide relevant information about the potential toxicity of a new chemical, analogue data may be useful for determining an appropriate exposure limit whenever (1) there is a defined endpoint such as a no observed adverse effect level (NOAEL), and (2) EPA is reasonably confident that the new chemical is not significantly more toxic than its analogue. The following is a brief discussion on how EPA generally uses analogue data (much as EPA would use direct data on the PMN substance itself) to set exposure limits in the New Chemicals Program.

1. Non-Cancer Effects

In a typical case in which analogue data would be used to set an exposure limit, the test endpoint such as the NOAEL or, less commonly, the LOAEL (lowest observed adverse effect level) in units of milligrams of chemical per kilogram of body weight per day (mg/kg/day) is divided by an appropriate uncertainty factor, the magnitude of which will depend on the type of study and its duration. The uncertainty factor is a product of several smaller uncertainty factors such as a factor for individual variability within exposed human populations and a factor to allow for greater human sensitivity to a chemical in comparison to a test species. The quotient, also expressed in units of mg/kg/day, may be considered a permissible daily dose, that is, a dose at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime. The permissible daily dose is multiplied by the weight of an average adult (70 kg) to convert the dose to the daily amount or mass absorbed per person (in units of mg/day). (If appropriate, this number may adjusted to account for less than 100% absorption.) The numerical value for the exposure limit in units of mg per cubic meter (mg/m^3) is obtained by dividing the daily amount in units of mg/day by 10 m^3, the volume of air inhaled in a typical eight hour work shift.

For example, if concern for a new chemical is based on data for an analogue indicating that it may be a developmental toxicant, then a limit for inhalation exposure could be set for the new

chemical using the analogue data. Assume that the NOAEL for developmental toxicity in an animal study was 100 mg/kg/day. The permissible daily human dose is 1 mg/kg/day obtained by dividing the NOAEL by 100, the uncertainty factor typically used for a developmental toxicity study with a NOAEL. The permissible amount absorbed per person per day is 70 mg, obtained by multiplying the permissible human dose by 70 kg. The inhalation exposure limit is 7 mg/m^3, obtained by dividing the permissible amount absorbed by 10 m^3. (Again, if appropriate, this number may adjusted to account for less than 100% absorption.)

2. Carcinogens

For non-cancer effects, the likelihood of observing adverse effects in test animals (and presumably man) is primarily dependent upon the daily dose in units of mg of toxicant per kilogram of body weight per day. For cancer, however, the probability of observing tumors is thought to be primarily a function of cumulative dose in terms of mg of carcinogen per kilogram of body weight per lifetime. This difference has an important bearing on the way a health-based exposure limit is derived for a carcinogen versus a non-carcinogen.

In regulating new chemicals that are potential carcinogens, OPPT risk managers have established a policy that a cancer risk of 10^{-4} or less is acceptable, that is, if exposure to a new chemical causes no more than 1 case of cancer in a population of 10,000 exposed workers, then that is considered an acceptable risk. To determine the maximum workplace exposure to a new chemical that will result in acceptable risk, the acceptable risk level, e.g. 10^{-4}, is divided by the slope factor of an appropriate analogue. The slope factor, a numerical measure of the activity of a carcinogen, is based on dose-response data from animal tests, but is adjusted to theoretically predict tumor response in man. The quotient, termed the lifetime average daily dose (LADD), is the dose of new chemical in units of milligrams of carcinogen per kilogram of body weight per day (mg/kg/day) such that, if a person were exposed over an entire lifetime, the probability of contracting cancer from exposure to the new chemical would be 10^{-4}. In fact, a worker is not exposed to a new chemical over a lifetime, rather exposure occurs over a 'work life' or a fraction of a work life. For risk assessment purposes, we usually assume that a worker works a maximum of 250 days out of a 365 day year, and a maximum of 40 years out of a 70 year lifespan. The LADD is therefore multiplied by the ratios 365/250 and 70/40 to arrive at a "work life average daily dose" in units of mg/kg/day. Beyond this point in the derivation of the exposure limit, the mathematical operations are identical to those discussed above for a non-cancer effect. The adjusted average daily dose is multiplied by the weight of an average adult worker (70 kg) and divided by 10 m^3, the volume of

air inhaled in an eight hour workday. The result of this calculation is the inhalation limit in units of mg/m^3. (Again, if appropriate, this number may adjusted to account for less than 100% absorption.)

For example, assume that a carcinogenic analogue of a new chemical has a slope factor of 0.01 $(mg/kg/day)^{-1}$. If the acceptable risk level is 10^{-4} then the lifetime average daily dose is 0.0l mg/kg/day (10^{-4} divided by 0.01 $(mg/kg/day)^{-1}$ = 0.01 mg/kg/day. To adjust for actual working days in a lifetime, 0.01 mg/kg/day is multiplied by 365/250 and 70/40 which results in an adjusted value of 0.026 mg/kg/day. Multiplication of the adjusted value by 70 kg and division by 10 m^3 results in an exposure limit of 0.2 mg/m^3. (Again, if appropriate, this number may adjusted to account for less than 100% absorption.)

The level calculated in the example above is quite low, and would be technically difficult to attain or to monitor. With weaker carcinogens the value of the inhalation limit would be somewhat higher, however, the slope factor chosen in the example is low, i.e., most carcinogens tested are more active. Thus for new chemicals which may be carcinogenic and which are manufactured, processed, or used throughout the year or a large fraction of the year, and have indefinite life spans, it may be difficult to attain or monitor an airborne concentration that would result in a risk of 10^{-4} or less.

Feasibility

Technological and economic feasibility of meeting an exposure limit will be a key consideration in "safer substitute/relative risk" cases where the company provides EPA with sufficient evidence that a new chemical substance is a desirable replacement for a more hazardous existing chemical. For such cases, EPA will strive to set a NCEL for the new chemical at a level that not only protects human health but also is feasible for the manufacturer. The Agency is very interested in working with industry to achieve net risk reduction.

ATTACHMENT II

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ATTACHMENT III

AUGUST 1991 DRAFT
TSCA '5(e) NEW CHEMICAL EXPOSURE LIMIT PROVISIONS