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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
LITTERA SCRIPTA MANET
1985

FEDERAL REGISTER

Vol. 79 Friday,
No. 197 October 10, 2014

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, et al.
Chemical Management and Permissible Exposure Limits (PELs); Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. OSHA 2012–0023]

RIN 1218–AC74

Chemical Management and Permissible Exposure Limits (PELs)

AGENCY: Occupational Safety and Health Administration (OSHA), DOL.

ACTION: Request for Information (RFI).

SUMMARY: OSHA is reviewing its overall approach to managing chemical exposures in the workplace and seeks stakeholder input about more effective and efficient approaches that addresses challenges found with the current regulatory approach. This review involves considering issues related to updating permissible exposure limits (PELs), as well as examining other strategies that could be implemented to address workplace conditions where workers are exposed to chemicals. The notice details the role of past court decisions on the Agency's current approach to chemical management for the purpose of informing stakeholders of the legal framework in which the Agency must operate. It then describes possible modifications of existing processes, along with potential new sources of data and alternative approaches the Agency may consider. The Agency is particularly interested in information about how it may take advantage of newer approaches, given its legal requirements. This RFI is concerned primarily with chemicals that cause adverse health effects from long-term occupational exposure, and is not related to activities being conducted under Executive Order 13650, Improving Chemical Facility Safety and Security.

DATES: Comments must be submitted by the following dates:

Hard copy: must be submitted (postmarked or sent) by April 8, 2015.

Electronic transmission or facsimile: must be submitted by April 8, 2015.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronically: Submit comments electronically at: *www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: Submissions no longer than 10-pages (including attachments) may be faxed to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, or messenger or courier service: Copies must be submitted in triplicate (3) to the OSHA Docket Office, Docket No. OSHA–2012–0023, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m. (E.T.).

Instructions: All submissions must include the Agency name and the OSHA docket number (*i.e.* OSHA–2012–0023). Submissions, including any personal information provided, are placed in the public docket without change and may be made available online at: *www.regulations.gov.* OSHA cautions against the inclusion of personally identifiable information (*e.g.,* social security number, birth dates).

If you submit scientific or technical studies or other results of scientific research, OSHA requests that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.,* consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific and technical analyses, OSHA requests that you disclose: (1) The nature of any financial relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party prior to its submission. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

Docket: To read or download submissions or other material in the docket go to: *www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the index; however, some information (*e.g.* copyrighted materials) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

FOR FURTHER INFORMATION CONTACT: *General information and press inquiries:* Mr. Frank Meilinger, Director, Office of Communications, U. S. Department of Labor, Room N–3647, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–1999; email *meilinger.francis2@dol.gov. Technical information:* Ms. Lyn Penniman, Office of Physical Hazards, OSHA, Room N–3718, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–1950; email *penniman.lyn@dol.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Purpose
II. Legal Requirements for OSHA Standards
A. Significant Risk of a Material Impairment: The *Benzene* Case
B. Technological and Economic Feasibility
C. The Substantial Evidence Test
III. History of OSHA's Efforts To Establish PELs
A. Adopting the PELs in 1971
B. The 1989 PELs Update
C. The 1989 PELs Update is Vacated
D. Revising OSHA's PELs in the Wake of the Eleventh Circuit Decision
IV. Reconsideration of Current Rulemaking Processes
A. Considerations for Risk Assessment Methods
1. Current Quantitative Risk Assessment Methods Typically Used by OSHA To Support 6(b) Single Substance Rulemaking
2. Proposed Tiered Approach to Risk Assessment in Support of Updating PELs for Chemical Substances
a. General Description and Rationale of Tiered Approach
b. Hazard Identification and Dose–Response Analysis in the Observed Range
c. Derivation of Low-End Toxicity Exposure (LETE)
d. Margin of Exposure (MOE) as a Decision Tool for Low Dose Extrapolation
e. Extrapolation Below the Observed Range
3. Chemical Grouping for Risk Assessment
a. Background on Chemical Grouping
b. Methods of Gap Analysis and Filling
i. Read-Across Method
ii. Trend Analysis
iii. QSAR
iv. Threshold of Toxicological Concern
4. Use of Systems Biology and Other Emerging Test Data in Risk Assessment
B. Considerations for Technological Feasibility

1. Legal Background of Technological Feasibility
2. Current Methodology of the Technological Feasibility Requirement
3. Role of Exposure Modeling in Technological Feasibility
a. Computational Fluid Dynamics Modeling To Predict Workplace Exposures
b. The Potential Role of REACH in Technological Feasibility
c. Technological Feasibility Analysis With a Focus on Industries with Highest Exposures
C. Economic Feasibility for Health Standards
1. OSHA's Current Approach to Economic Feasibility
2. Alternative Approaches to Formulating Health Standards that Might Accelerate the Economic Feasibility Analysis
3. Alternative Analytical Approaches to Economic Feasibility in Health Standards
4. Approaches to Economic Feasibility Analysis for a Comprehensive PELs Update
V. Recent Developments and Potential Alternative Approaches
A. Sources of Information About Chemical Hazards
1. EPA's High Production Volume Chemicals
2. EPA's CompTox and ToxCast
3. Production and Use Data Under EPA's Chemical Data Reporting Rule
4. Structure-Activity Data for Chemical Grouping
5. REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals in the European Union (EU)
B. Non-OEL Approaches to Chemical Management
1. Informed Substitution
2. Hazard Communication and the Globally Harmonized System (GHS)
3. Health Hazard Banding
4. Occupational Exposure Bands
5. Control Banding
6. Task-based Exposure Assessment and Control Approaches
VI. Authority and Signature
Appendix A: History, Legal Background and Significant Court Decisions
Appendix B: 1989 PELs Table
List of References by Exhibit Number

List of Acronyms: Request for Information on Chemical Management and Permissible Exposure Limits

ACGIH American Conference of Governmental Industrial Hygienists
ADI Allowable Daily Intake
AIHA American Industrial Hygiene Association
AISI American Iron and Steel Institute
ANSI American National Standards Institute
APHA American Public Health Association
ATSDR Agency for Toxic Substances Disease Registry
BAuA Federal Institute for Occupational Safety and Health (Germany)
BMD Benchmark Dose
BMDL Benchmark Dose Low
BMR Benchmark Response
CDR Chemical Data Reporting
CFD Computational Fluid Dynamics
COSHH Control of Substances Hazardous to Health (U.K.)
CrVI Hexavalent Chromium
CSTEE Scientific Committee on Toxicity, Ecotoxicity and the Environment (E.U.)
CT Control Technology
DfE Design for the Environment (EPA)
DHHS Department of Health and Human Services (U.S.)
DMEL Derived Minimal Effect Level
DNEL Derived No Effect Level
DOE Washington Department of Ecology
DOL Department of Labor (U.S.)
ECB European Chemicals Bureau (E.U.)
ECHA European Chemicals Agency (E.U.)
EPA Environmental Protection Agency (U.S.)
ES Exposure Scenario
EU European Union
FDA Food and Drug Administration (U.S.)
GAO Government Accountability Office (U.S.)
GHS Globally Harmonized System for the Classification and Labeling of Chemicals
HazCom 2012 Revised OSHA Hazard Communication Standard
HCS Hazard Communication Standard (OSHA)
HHE Health Hazard Evaluation (NIOSH)
HPV High Production Volume (EPA)
HPVIS High Production Volume Information System (EPA)
HSE Health and Safety Executive (U.K.)
HTS High Throughput Screening
IFA Federation of Institutions for Statutory Accident Insurance and Prevention (Germany)
IMIS Integrated Management Information System (OSHA)
IPCS World Health Organization International Programme on Chemical Safety
IRIS Integrated Risk Information System (EPA)
ISTAS Institute of Work, Environment, and Health (Spain)
ITC Interagency Testing Committee (EPA TSCA)
IUR Inventory Update Reporting
LETE Low-end Toxicity Exposure
LOAEL Lowest Observed Adverse Effect Level
LOD Limit of Detection
LTFE Lowest Technologically Feasible Exposure
MA DEP Massachusetts Department of Environmental Protection
MIBK Methyl isobutyl ketone
MOA Modes of Action
MOE Margin of Exposure
MRL Minimal Risk Level
NAICS North American Industry Classification System
NCGC National Institutes of Health Chemical Genomics Center
NIEHS National Institute of Environmental Health Sciences (U.S.)
NIOSH National Institute for Occupational Safety and Health (U.S.)
NIST National Institute of Standards and Technology (U.S.)
NMCSD Navy Medical Center San Diego
NOAEL No Observed Adverse Effect Level
NOES National Occupational Exposure Survey
NORA National Occupational Research Agenda (NIOSH)
NPRM Notice of Proposed Rulemaking (OSHA)
NRC National Research Council (U.S., private)
NTP National Toxicology Program (U.S.)
OECD Organization for Economic Cooperation and Development (multiple countries, private)
OEL Occupational Exposure Limit
OPPT Office of Pollution Prevention and Toxics (EPA)
OSHA Occupational Safety and Health Administration
OTA Massachusetts Office of Technical Assistance and Technology
PBT Persistent, Bioaccumulative and Toxic
PBZ Personal Breathing Zone
PCRARM (EPA) Presidential/Congressional Commission on Risk Assessment and Risk Management
PEL Permissible Exposure Limits
PMN Pre-manufacture Notification (EPA)
PNEC Predicted No Effect Concentration
POD Point of Departure
PPE Personal Protective Equipment
PPM Parts Per Million
QCAT Quick Chemical Assessment Tool (DOE)
QSAR Quantitative Structure-Activity Relationship
REACH Registration, Evaluation, Authorization and Restriction of Chemicals (E.U.)
REL Recommended Exposure Level
RfC Reference Concentration
RFI Request for Information
SAR Structural Activity Relation
SBREFA Small Business Regulatory Enforcement Fairness Act (U.S.)
SDS Safety Data Sheet
SEP Special Emphasis Program
SIC Standards Industrial Classification
SIDS Screening Information Data Set (OECD)
STEL Short-term Exposure Limit
TLV Threshold Value Limit (ACGIH)
TSCA Toxic Substances Control Act (EPA)
TTC Threshold of Toxicological Concern
TWA Time-weighted Average
vPvB Very Persistent and Very Bioaccumulative
WEEL Workplace Environmental Exposure Level (AIHA)

I. Purpose

The purpose of this Request for Information (RFI) is to present background information and request comment on a number of technical issues related to aspects of OSHA's rulemaking process for chemical hazards in the workplace. In particular, the purpose of the RFI is to:

- Review OSHA's current approach to chemical regulation in its historical context;
- Describe and explore other possible approaches that may be relevant to future strategies to reduce and control exposure to chemicals in the workplace; and
- Inform the public and obtain public input on the best approaches for the

Agency to advance the development and implementation of approaches to reduce or eliminate harmful chemical exposures in the 21st century workplace.

By all estimates, the number of chemicals found in workplaces today far exceeds the number which OSHA regulates, and is growing rapidly. There is no single source recording all chemicals available in commerce. Through its Chemical Data Reporting Rule, EPA collects information on chemicals manufactured or imported at a single site at 25,000 pounds or greater; currently this number exceeds 7,674 chemicals (U.S. EPA, 2013a; *Ex. #1*)

The American Chemistry Council estimates that approximately 8,300 chemicals (or about 10 percent of the 87,000 chemicals in the TSCA inventory) are actually in commerce in significant amounts (Hogue, 2007; *Ex. #2*). By contrast the European Chemicals Agency database contains 10,203 unique substances (as of 9/12/2013) (ECHA, 2013; *Ex. #3*). Of these, OSHA has occupational exposure limits for only about 470 substances. Most of these are listed as simple limits and appear in tables (referred to as ''Z-tables'') in 29 CFR 1910.1000, *Air Contaminants,* Subpart Z, *Toxic and Hazardous Substances; Ex. #4.* Approximately 30 have been adopted by OSHA as a part of a comprehensive standard, and include a number of additional requirements such as regulated areas, air sampling, medical monitoring, and training However, with few exceptions, OSHA's permissible exposure limits, (PELs), which specify the amount of a particular chemical substance allowed in workplace air, have not been updated since they were established in 1971 under expedited procedures available in the short period after the OSH Act's adoption (see 29 CFR 1910.1000; *Ex. #4,* 1915.1000; *Ex. #5,* and 1926.55; *Ex. #6*). Yet, in many instances, scientific evidence has accumulated suggesting that the current limits are not sufficiently protective. Although OSHA has attempted to update its PELs, the Agency has not been successful, except through the promulgation of a relatively few substance-specific health standard rulemakings (e.g., benzene, cadmium, lead, and asbestos).

The most significant effort to update the PELs occurred in 1989 when OSHA tried to update many of its outdated PELs and to create new PELs for other substances in a single rulemaking covering general industry PELs. After public notice and comment, the Agency published a general industry rule that lowered PELs for 212 chemicals and added new PELs for 164 more (54 FR 2332; *Ex. #7*). Appendix B to this Request for Information contains the table of PELs from the 1989 Air Contaminants Final Rule. The table includes both the PELs originally adopted by OSHA in 1971 and the PELs established under the 1989 final rule. While the Agency presented analyses of the risks associated with these chemicals, as well as the analyses of the economic and technological feasibility of the proposed limits for these chemicals, these analyses were not as detailed as those OSHA would have prepared for individual rulemakings. The final rule was challenged by both industry and labor groups. The 1989 PEL update was vacated by the Eleventh Circuit Court of Appeals because it found that OSHA had not made sufficiently detailed findings that each new PEL would eliminate significant risk and would be feasible in each industry in which the chemical was used. (*AFL–CIO* v. *OSHA, 965 F.*2d 962 (11th Cir. 1992) (the *Air Contaminants* case; *Ex. #8*). This decision is discussed further below and in Appendix A.

Despite these challenges, health professionals and labor and industry groups have continued to support addressing PELs which may be outdated and or inconsistent with the best available current science. The 1989 Air Contaminants rulemaking effort was supported by the American Industrial Hygiene Association (AIHA), the American Conference of Governmental Industrial Hygienists (ACGIH), and the American Public Health Association (APHA), among many other professional organizations and associations representing both industry and labor. In an October 2012 survey, members of the AIHA identified updating OSHA PELs as their number one policy priority. The U.S. Chamber of Commerce, in a letter dated April 8, 2011 to then Deputy Secretary of Labor, Seth Harris, also supported updating OSHA's PELs.

Much has changed in the world since the OSH Act was signed in 1970. However, workers are essentially covered by the same PELs as they were forty years ago. And while OSHA has been given no new tools or increased resources to control workplace exposures, it has had to conduct increasingly complex analyses, which has effectively slowed the process. The purpose of this RFI is for OSHA to solicit information as to the best approach(es) for the Agency to help employers and employees devise and implement risk management strategies to reduce or eliminate chemical exposures in the 21st century workplace environment. This is likely to involve a multi-faceted plan that may include changing or improving OSHA policies and procedures regarding the derivation and implementation of PELs, as well as pursuing new strategies to improve chemical management in the workplace. The Agency is publishing this notice to inform the public of its consideration of these issues, as well as solicit public input that can be used to inform further deliberations, and the determination of an appropriate approach.

II. Legal Requirements for OSHA Standards

In the past, OSHA has received many suggestions for updating its PELs, but these suggestions often do not take account of the requirements imposed by the OSH Act, and thus have been of limited value to OSHA. OSHA is providing an overview of its legal requirements for setting standards in order to help commenters responding to this RFI to provide suggestions that can satisfy these requirements. This section summarizes OSHA's legal requirements, which are discussed in greater detail in Appendix A. The next section provides an overview of OSHA's previous attempts to update the PELs.

Section 6(b) of the OSH Act (*Ex. #9*) provides OSHA with the authority to promulgate health standards. It specifies procedures that OSHA must use to promulgate, modify, or revoke its standards, including publishing the proposed rule in the **Federal Register**, providing interested persons an opportunity to comment, and holding a public hearing upon request. However, much of the labor and analysis that goes into the final rule starts before the publication of the proposal. Section 6(b)(5) of the Act specifies:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

In general, as this provision has been construed by the courts, any workplace

health standard adopted by OSHA must meet the following requirements:

(1) The standard must substantially reduce a significant risk of material harm.

(2) Compliance with the standard must be technically feasible. This means that the protective measures required by the standard currently exist, can be brought into existence with available technology, or can be created with technology that can reasonably be developed.

(3) Compliance with the standard must be economically feasible. This means that the standard will not threaten the industry's long term profitability or substantially alter its competitive structure.

(4) It must reduce risk of adverse health to workers to the extent feasible.

(5) The standard must be supported by substantial evidence in the record, consistent with prior agency practice or is supported by some justification for departing from that practice.

The significant risk, economic and technological feasibility, and substantial evidence requirements are of particular relevance in setting PELs, and are discussed further below.

A. Significant Risk of a Material Impairment: The Benzene Case

The significant risk requirement was first articulated in a plurality decision of the Supreme Court in *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980), commonly referred to as the *Benzene* case. The petitioners challenged OSHA's rule lowering the PEL for benzene from 10 ppm to 1 ppm. In support of the new PEL, OSHA found that benzene caused leukemia and that the evidence did not show that there was a safe threshold exposure level below which no excess leukemia would occur; OSHA chose the new PEL of 1 ppm as the lowest feasible exposure level. The *Benzene* Court rejected OSHA's approach, finding that the OSH Act only required that employers ensure that their workplaces are safe, that is, that their workers are not exposed to ''significant risk[s] of harm.'' 448 U.S. at 642 (*Ex. #10*). The Court also made it clear that it is OSHA's burden to establish that a significant risk is present at the current standard before lowering a PEL, stating that the burden of proof is normally on the proponent. Thus, the Court held, before promulgating a health standard, OSHA is required to make a ''threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' before it can adopt a new standard. Id.

Although the Court declined to establish a set test for determining whether a workplace is unsafe, it did state that a significant risk was one that a reasonable person would consider significant and ''take appropriate steps to decrease or eliminate.'' 448 U.S. at 655. For example, it said, a one in a 1,000 risk would satisfy the requirement. However, this example was merely an illustration, not a hard line rule. The Court made it clear that determining whether a risk was ''significant'' was not a ''mathematical straitjacket'' and did not require the Agency to calculate the exact probability of harm. Id. The 1 ppm PEL was vacated because OSHA had not made a significant risk finding at the 10 ppm level.

Following the *Benzene* case, OSHA has satisfied the significant risk requirement by estimating the risk to workers subject to a lifetime of exposure at various possible exposure levels. These estimates have typically been based on quantitative risk assessments in which OSHA, as a general policy, has considered an excess risk of one death per 1000 workers over a 45-year working lifetime as clearly representing a significant risk. However, the *Benzene* case does not require OSHA to use such a benchmark. In the past, OSHA has stated that a lower risk of death could be considered significant. *See, e.g.,* Preamble to Formaldehyde Standard, 52 FR 46168, 46234 (suggesting that risk approaching six in a million could be viewed as significant). (*Ex. #11*)

B. Technological and Economic Feasibility

Under section 6(b)(5) of the Act, a standard must protect against significant risk, ''to the extent feasible, and feasibility is understood to have both technological and economic aspects. A standard is technologically feasible if ''a typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most operations.'' *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1981) (''*Lead I''; Ex. #12*). OSHA must show the existence of ''technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines.'' Id. Where the Agency presents ''substantial evidence that companies acting vigorously and in good faith can develop the technology,'' the Agency is not bound to the technological status quo, and ''can require industry to meet PELs never attained anywhere.'' Id. at 1264–65.

Some courts have required OSHA to determine whether a standard is technologically feasible on an industry-by-industry basis, *Color Pigments Manufacturers Assoc.* v. *OSHA,* 16 F.3d 1157, 1162–63 (11th Cir. 1994; *Ex. #13*); AFL–CIO v. OSHA, 965, F.2d 962, 981–82 (11th Cir. 1992) (*Air Contaminants; Ex. #8*). However, another court has upheld technological feasibility findings based on the nature of an activity across many industries rather than on an industry-by-industry basis, *Public Citizen Health Research Group* v. *United States Department of Labor,* 557 F.3d 165,178–79 (3d Cir. 2009; *Ex. #14*).

With respect to economic feasibility, the courts have stated ''A standard is feasible if it does not threaten massive dislocation to . . . or imperil the existence of the industry.'' *Lead I,* 647 F.2d at 1265 *(Ex. #12).* In order to show this, OSHA should ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.'' Id. at 1266. However, ''[T]he court probably cannot expect hard and precise estimates of costs. Nevertheless, the agency must of course provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry.'' Id.

While OSHA is not required to show that all companies within an industry will be able to bear the burden of compliance, at least one court has held that OSHA is required to show that the rule is economically feasible on an industry-by-industry basis. *Air Contaminants,* 965 F.2d at 982, 986. *(Ex. #8)*

C. The Substantial Evidence Test

The ''substantial evidence test'' is used by the courts to determine whether OSHA has reached its burden of proof for policy decisions and factual determinations. ''Substantial evidence'' is defined as ''such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'' *American Textile Mfrs. Inst., Inc.* v. *Donovan,* 452 U.S. 490, 522 (1981; *Ex. #15*) (quoting *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 477 (1951); *Ex. #16*). The substantial evidence test does not require ''scientific certainty'' before promulgating a health standard (*AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 656 (1980); *Ex. 10*), but the test does require OSHA to ''identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any

assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument.'' *Lead I,* 647 F.2d. at 1207. (*Ex. #12*)

III. History of OSHA's Efforts To Establish PELs

The history of OSHA's PELs has three stages. First, OSHA adopted its current PELs in 1971, shortly after coming into existence. Second, OSHA attempted to update its PELs wholesale in 1989, but that effort was rejected by the Eleventh Circuit Court of Appeals in 1992. Third, OSHA has made subsequent, smaller efforts to update certain PELs, but those efforts have never come to fruition. This history is summarized below, and discussed in further detail in Appendix A.

A. Adopting the PELs in 1971

Under section 6(a), OSHA was permitted an initial two-year window after the passage of the OSH Act to adopt ''any national consensus standard and any established Federal standard'' 29 U.S.C 655(6)(a). OSHA used this authority in 1971 to establish PELs that were adopted from federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits were selected based on ACGIH's 1968 list of Threshold Limit Values (TLVs). In addition, about 25 additional exposure limits recommended by the American Standards Association (now called the American National Standards Institute) (ANSI), were adopted as national consensus standards.

These standards were intended to provide initial protections for workers from what the Congress deemed to be the most dangerous workplace threats. Congress found it was ''essential that such standards be constantly improved and replaced as new knowledge and techniques are developed.'' S. Rep. 91–1282 at 6. (*Ex. #17*) However, because OSHA has been unable to update the PELs, they remain frozen at the levels at which they were initially adopted. OSHA's PELs are also largely based on acute health effects and do not take into consideration newer research regarding chronic health effects occurring at lower occupational exposures.

B. The 1989 PELs Update

In 1989, OSHA published the *Air Contaminants* final rule, which remains the Agency's most significant attempt at updating the PELs (54 FR 2332). (*Ex. #7*) Unlike typical substance-specific rulemakings, where OSHA develops a comprehensive standard, the *Air Contaminants* final rule was only intended to update existing PELs or to add PELs for substances within established boundaries. After extensive review of all available sources of occupational exposure limits (OELs), OSHA selected the ACGIH's 1987–88 TLVs as the boundaries for identifying the substances that would be included in the proposed rule. OSHA proposed 212 more protective PELs and new PELs for 164 substances not previously regulated. In general, rather than performing a quantitative risk assessment for each chemical, the agency looked at whether studies showed excess effects of concern at concentrations lower than allowed under the existing standard. Where they did, OSHA made a significant risk finding and either set a PEL (where none existed previously) or lowered the existing PEL. These new PELs were based on Agency judgment, taking into account the existing studies and, as appropriate, safety factors. Safety factors (also called uncertainty factors) are applied to the lowest level an effect is seen or to a level where no effects are seen to derive a PEL.

In order to determine whether the *Air Contaminants* rule was feasible, OSHA prepared the regulatory impact analysis. As part of the analysis, OSHA performed an industry survey as well as site visits. The survey was the largest survey ever conducted by OSHA and included responses from 5,700 firms in industries believed to use chemicals addressed in the scope of the *Air Contaminants* proposal. (*Ex. #18)* It was designed to focus on industry sectors that potentially had the highest compliance costs, identified through an analysis of existing exposure data at the four-digit SIC (Standards Industrial Classification) code level. OSHA analyzed the data collected to determine whether the updated PELs were both technologically and economically feasible for each industry sector covered.

For technological feasibility, OSHA found that ''in the overwhelming majority of situations where air contaminants [were] encountered by workers, compliance [could] be achieved by applying known engineering control methods, and work practice improvements.'' 54 FR at 2789; *Ex. #7.* For economic feasibility, OSHA assessed the economic impact of the standard on industry profits at the two-digit SIC code level, and found the economic impact not to be significant, and the new standard therefore economically feasible.

In the *Air Contaminants* final rule, OSHA summarized the health evidence for each individual substance, discussed over 2,000 studies, reviewed and addressed all major comments submitted to the record, and provided a rationale for each new PEL chosen. OSHA estimated that over 21 million employees were potentially exposed to hazardous substances in the workplace and over 4.5 million employees were exposed to levels above the applicable exposure limits. OSHA projected that the final rule would result in a potential reduction of over 55,000 lost workdays due to illnesses per year and that annual compliance with this final rule would prevent an average of 683 fatalities annually from exposures to hazardous substances.

C. The 1989 PELs Update Is Vacated by the Court of Appeals

The update to the *Air Contaminants* standard generally received widespread support from both industry and labor. However, there was dissatisfaction on the part of some industry representatives and union leaders, who brought petitions for review challenging the standard. For example, some industry petitioners argued that OSHA's use of generic findings, the inclusion of so many substances in one rulemaking, and the allegedly insufficient time provided for comment by interested parties created a record inadequate to support the new set of PELs. In contrast, the unions challenged the approach used by OSHA to promulgate the standard and argued that several PELs were not protective enough. The unions also asserted that OSHA's failure to include any ancillary provisions, such as exposure monitoring and medical surveillance, prevented employers from ensuring the exposure limits were not exceeded, and resulted in less-protective PELs.

Although only 23 of the 428 PELs were challenged, the court ultimately decided to vacate the entire rulemaking, finding that ''OSHA [had] not sufficiently explained or supported its threshold determination that exposure to these substances at previous levels posed a significant risk of these material health impairments or that the new standard eliminates or reduces that risk to the extent feasible.'' *Air Contaminants* 965 F.2d at 986–987; *Ex. #8*

With respect to significant risk, the court held that OSHA had failed to ''explain why the studies mandated a particular PEL chosen.'' Id. at 976. Specifically, the court stated that OSHA failed to quantify the risk from individual substances and merely provided conclusory statements that the new PEL would reduce a significant risk

of material health effects.'' Id. at 975. Further, the court rejected OSHA's argument that it had relied on safety factors in setting the new PELs, stating that OSHA had not adequately supported their use. The court observed that ''the difference between the level shown by the evidence and the final PEL is sometimes substantial.'' Id. at 978. It said that OSHA had not indicated ''how the existing evidence for individual substances was inadequate to show the extent of risk for these factors'' and that the agency had ''failed to explain the method by which its safety factors were determined.'' Id. ''OSHA may use assumptions but only to the extent that those assumptions have some basis in reputable scientific evidence,'' the court concluded. Id. at 978–79.

The *Eleventh Circuit* court also rejected OSHA's technological feasibility findings. The Agency had made these findings mainly at the two-digit SIC level, but also at the three- and four- digit level where appropriate given the processes involved. The court rejected this approach, finding that OSHA failed to make industry-specific findings or identify the specific technologies capable of meeting the proposed limit in industry-specific operations. Id. at 981. While OSHA had identified primary air contaminant control methods: Engineering controls, administrative controls and work practices and personal protective equipment, the agency, ''only provided a general description of how the generic engineering controls might be used in the given sector.'' Id. Though noting that OSHA need only provide evidence sufficient to justify a ''general presumption of feasibility,'' the court held that this ''does not grant OSHA license to make overbroad generalities as to feasibility or to group large categories of industries together without some explanation of why findings for the group adequately represents the different industries in that group.'' Id. at 981–82.

The court rejected OSHA's economic feasibility findings for similar reasons. As discussed above, OSHA supported its economic feasibility findings for the 1989 Air Contaminants rule based primarily on the results of a survey of over 5700 businesses, summarizing the projected cost of compliance at the two-digit SIC industry sector level. The court held that OSHA was required to show that the rule was economically feasible on an industry-by industry basis, and that OSHA had not shown that its analyses at the two-digit SIC industry sector level were appropriate to meet this burden. Id. at 982. ''[A]verage estimates of cost can be extremely misleading in assessing the impact of particular standards on individual industries'' the court said, and ''analyzing the economic impact for an entire sector could conceal particular industries laboring under special disabilities and likely to fail as a result of enforcement.'' Id. While OSHA might ''find and explain that certain impacts and standards do apply to entire sectors of an industry'' if ''coupled with a showing that there are no disproportionately affected industries within the group,'' OSHA had not explained why its use of such a ''broad grouping was appropriate.'' Id. at 982 n.28, 983.

D. Revising OSHA's PELs in the Wake of the Eleventh Circuit Decision

In the wake of the Eleventh Circuit's decision, OSHA has generally pursued a conservative course in satisfying its judicially imposed analytical burdens. The set of resulting analytical approaches OSHA has engaged in is highly resource-intensive and has constrained OSHA's ability to prioritize its regulatory efforts based on risk of harm to workers. In 1995, OSHA made its first attempt following the *Air Contaminants* ruling to update a smaller number of PELs using a more rigorous analysis of risk, workplace exposures, and technological and economic feasibility. (*Ex. #20)* OSHA and the National Institute for Occupational Safety and Health (NIOSH) conducted preliminary research on health risks associated with exposure and extent of occupational exposure. Sixty priority substances were identified for further examination and twenty of the sixty substances were selected to form a priority list. Early in 1996, the Agency announced its plans for a stakeholder meeting, and identified the twenty priority substances, as well as several risk-related discussion topics. (*Ex. #21)* During the meeting, almost all stakeholders from industry and labor agreed that the PELs needed to be updated; however, not one group completely supported OSHA's suggested approach. Overall, many of the stakeholders did not support the development of a list of priority chemicals targeted for potential regulation and felt there was a lack of transparency in the process for selecting the initial chemicals.

In response to stakeholder input and OSHA's research, the agency selected seven of the 20 substances discussed at the stakeholder meeting for detailed analysis of risks and feasibility. The chemicals selected were: (i) Glutaraldehyde, (ii) carbon disulfide, (iii) hydrazine, (iv) perchloroethylene, (v) manganese, (vi) trimellitic anhydride, and (vii) chloroprene. Quantitative risk assessments were performed in-house, and research (including site visits) was undertaken to collect detailed data on uses, worker exposures, exposure control technology effectiveness, and economic characteristics of affected industries.

The research and analysis were carried out over several years, after which OSHA decided not to proceed with rulemaking. (*Ex. #22)* This decision was influenced by findings that (i) prevalence and intensity of worker exposures for some of the substances (*e.g.,* carbon disulfide and hydrazine) had declined substantially since the 1989 rule was promulgated; (ii) industry had voluntarily implemented controls to reduce the exposure to safe levels; and (iii) for others, substantial Agency resources would have been required to fully assess technological and economic impacts.

In 1997, OSHA held another meeting with industry and labor on the proposed PEL development process. Although the project did not result in a rulemaking to revise the PELs, OSHA gained valuable experience in developing useful approaches for quantifying non-cancer health risks through collaboration with external reviewers in scientific peer reviews of its risk analyses. OSHA is now examining ways to better address chemical exposures given current resource constraints and regulatory limitations.

For readers who are interested in a more detailed account of the legislation and court decisions that shaped OSHA's current regulatory framework, Appendix A to this Request for Information, *History, Legal Background and Significant Court Decisions,* provides additional information. Readers may want to consult Appendix A as they frame responses to the questions posed in this Request for Information.

IV. Reconsideration of Current Rulemaking Processes

As reviewed in Section II (Legal Requirements for OSHA Standards) and Section III (History of OSHA's Efforts to Establish PELs), OSHA has to use the best available evidence to make findings of significant risk, substantial reductions in risk, and technological and economic feasibility under the Act. This section reviews how interpretation of 6(b)(5) and subsequent case law has resulted in the methods it uses when developing risk, technical feasibility, and economic findings as well as the evidence OSHA has used in the past to make these findings (*i.e.,* OSHA's use of

formal risk assessment modeling to evaluate significant risk, and the Agency's use of worker exposure data and exposure control effectiveness data to evaluate technical feasibility and costs of compliance).

This section also reviews developments in science and technology and how these new advancements may improve the scientific basis for making findings of significant risk, technical feasibility, and economic feasibility. As an example, the National Academies of Science has released extensive reviews of advances in science, toxicology, and risk and exposure assessment and evaluated how the Federal government can potentially utilize these advancements in its decision-making processes (NRC, 2012; *Ex. #23,* NRC, 2009; *Ex. #24,* NRC, 2007; *Ex. #25*). While new technologies will advance the public's understanding in these critical areas, the Agency has obligations under the OSH Act to make certain findings under 6(b)(5), as discussed above in Section III. How OSHA might utilize these new developments to meet the Agency's evidentiary burden will be discussed in this section.

A. Considerations for Risk Assessment Methods

1. Current Quantitative Risk Assessment Methods Typically Used by OSHA To Support 6(b) Single Substance Rulemaking

As discussed in Section III, the Supreme Court requires OSHA to determine that a significant risk exists before adopting an occupational safety and health standard. While the Court did not stipulate a means to distinguish significant from insignificant risks, it broadly described the range of risks OSHA might determine to be significant:

> It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*Benzene,* 448 U.S. at 655). (*Ex. #10*),

OSHA has interpreted the Court's example to mean that a 1 in 1000 risk of serious illness is significant, and has used this measure to guide its significance of risk determinations. For example, OSHA's risk assessment for hexavalent chromium estimated that a 45-year occupational exposure at the PEL of 5μg/m^3 would lead to more than 10 lung cancer cases per 1000 workers exposed. Because this risk exceeds the value of one case of lung cancer per 1000 exposed workers, OSHA found it to be significant. The significance of risk determinations of other rules since the *Benzene* decision have typically followed a similar logic.

Over the three decades since the *Benzene* decision, OSHA has gradually built up a highly rigorous approach to derive quantitative estimates of risk such as those found in the hexavalent chromium preamble. First, the Agency reviews the available exposure-response data for a chemical of interest. It evaluates the available data sets and identifies those best suited for quantitative analysis. Using the best available data, the Agency then conducts extensive statistical analyses to develop an exposure-response model that is able to extrapolate probability of disease at exposures below the observed data. Once the model is developed, OSHA conducts further analyses to evaluate the sensitivity of the model to error and uncertainties in the modeling inputs and approach. The exposure-response model is used to generate estimates of risk associated with a working lifetime of occupational exposure to the chemical of interest over a range of PEL options that often include exposure levels below those considered to be technologically feasible. The entire risk assessment has always been subject to peer review, from choice of data set(s) through generation of lifetime risk estimates.When the proposed rule is released for comment, it receives additional scrutiny from the scientific community, stakeholders, and the general public. The Agency uses the feedback of the peer review panel and public comment at the time of proposal to further test and develop the risk analysis.

This model-based approach to risk assessment has a number of important advantages. The quantitative risk estimates can be easily compared with the level of 1 in 1000 that the Court cited as an example of significant risk. Sometimes, the best available data come from worker or animal populations with exposure levels far above the technologically feasible levels for which OSHA must evaluate risk, and a risk model is used to extrapolate from high to low exposures. When large, high-quality exposure-response data sets are available, a rigorous quantitative analysis can yield robust and fairly precise risk estimates to inform public understanding and debate about the health benefits of a new or revised regulation. However, there are also drawbacks to the model-based approach, and there are situations where a modeling analysis may not be necessary or appropriate for OSHA to make the significance of risk determination to support a new or revised regulation. Model-based risk analyses tend to require a great deal of Agency time and resources.

In some cases, the model-based approach is essential to OSHA's significant risk determination, because it is not evident prior to a modeling analysis whether there is significant risk at current and technologically-feasible exposures. In other cases, however, it may be evident from the scientific literature or other readily available evidence that risk at the existing PEL is clearly significant and that it can be substantially reduced by a more stringent regulation without the need for quantitative estimates extrapolated from an exposure-response model. In addition to reducing significant risk of harm, the OSH Act also directs the Agency to determine that health standards for toxic chemicals are feasible. At times, it is evident without extensive analysis that the most stringent PEL feasible can only reduce, not eliminate, significant risk. In such cases, the value of a model-based quantitative risk assessment may not warrant the Agency time and resources that model-based risk assessment requires.

In situations described above where the PEL may be set at the lowest feasible level, OSHA believes that it can establish significant risk more efficiently instead of relying on probabilistic estimates from dose-response modeling as described above. OSHA is exploring a number of more flexible, scientifically accepted approaches that may streamline the risk assessment process and increase the capacity to address a greater number of chemicals.

Question IV.A.1: OSHA seeks input on the risk assessment process described above. When is a model-based analysis necessary or appropriate to determine significance of risk and to select a new or revised PEL? When should simpler approaches be employed? Are there specific approaches OSHA should consider using when a model-based analysis is not required? To the extent possible, please provide detailed explanation and examples of situations when a model-based risk analysis is or is not necessary to determine significance of risk and to develop a new standard.

2. Proposed Tiered Approach to Risk Assessment in Support of Updating PELs for Chemical Substances

a. General Description and Rationale of Tiered Approach

OSHA is considering a tiered process to exposure-response assessment that may enable the agency to more efficiently make the significant risk findings needed to establish acceptable PELs for larger numbers of workplace chemicals. The approach involves three stages: dose-response analysis in the observed range, margin of exposure determination, and exposure-response extrapolation (if needed). The process overlaps with the risk-based methodologies employed by EPA IRIS, NIOSH, the Agency for Toxic Substances Disease Registry (ATSDR), the European Union Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program, and other organizations that recommend chemical toxicity values or exposure levels protective of human health. The first step is dose-response analysis in the observed range. During this step, OSHA analyzes exposures (or doses) and adverse outcomes from human studies or animal bioassays, particularly at the lower end of the exposure range. This involves the derivation of a ''low-end toxicity exposure'' (LETE), which is discussed further in section IV.A.2.c. below.

The second step is margin of exposure determination, where LETEs are compared with the range of possible exposure limits that OSHA believes to be feasible for the new or proposed standard. Typically, there is a close and ongoing dialogue between those OSHA technical staff and management responsible for the risk assessment and their counterparts responsible for the feasibility analyses as the separate determinations are being simultaneously developed. Feasibility analyses, in particular, can take years of research, including site visits and industry surveys. In many of OSHA's rulemakings, the lowest feasible PEL can only reduce, not eliminate, significant risk. Thus, OSHA sets many PELs at the lowest feasible level, and not at a level of occupational exposure considered to be without significant risk. This significant risk orientation differs from other Federal Agencies, such as EPA and ATSDR that set environmental exposure levels determined to be health protective without consideration of feasibility.

OSHA is considering using a margin of exposure (MOE) approach to compare the LETE with the range of feasible exposure limits. If the MOE indicates the range of feasible exposures is in close proximity to the exposures where toxicity is observed (*i.e.,* a low MOE) then it may not be necessary to extrapolate exposure-response below the observed range in order to establish significant risk. In this situation, OSHA would set the PEL at the exposure level it determines to be feasible and the dose-response analysis in the observed range should be sufficient to support Agency significant risk findings. The PEL is set at the lowest feasible level, with the understanding that significant risk of adverse health outcomes remains at the new PEL. In the traditional risk assessment approach described previously, OSHA uses quantitative exposure-response modeling to estimate risks below the range of observed exposure, without regard to whether such exposures are considered to be technologically feasible. If the lowest technologically feasible workplace exposures are determined to be far below the LETE (*i.e.,* a high MOE), an exposure-response model would be needed to determine significant risk at exposures below the observed range and to set the appropriate PEL.

If there is a high MOE, then the Agency would move onto the final stage of the tiered approach, which is exposure-response extrapolation, where the dose-response relationship is extrapolated outside the observed range. Many regulatory agencies, such as EPA, choose to extrapolate outside the observed range for non-cancer health outcomes by applying a series of extrapolation factors, also called uncertainty factors, to an observed low-end toxicity value, referred to as a *point of departure* (POD). The POD is very similar to the LETE described above. The distinction between these toxicity values is discussed later in the subsection. The extrapolation factors are further explained below.

In many instances, EPA does not use the extrapolation factor approach for cancer effects. Rather, EPA uses dose-response modeling in the observed range and a linear extrapolation below the observed range to derive a unit risk (*i.e.,* risk per unit of exposure). As described previously, OSHA also uses dose-response modeling to extrapolate risk below the observed range for carcinogens as was done for hexavalent chromium (71 FR 10174–10221; *Ex. #26*) and methylene chloride (62 FR 1516–1560; *Ex. #27*). There is a reasonable body of scientific evidence that genotoxic carcinogens, and perhaps other carcinogenic modes of action, display linear, non-threshold behavior at very low dose levels. OSHA also uses dose-response modeling to extrapolate risk below the observed range for carcinogens. As mentioned earlier, the Agency develops appropriate exposure-response models (linear or non-linear) that best fit the existing data and are consistent with available information on mode of action. The models can be used to extrapolate risk associated with a working lifetime at occupational exposures below the observed range.

In some situations, the LETE is further adjusted to calculate worker equivalent exposures and to account for how the chemical is absorbed, distributed, and metabolized, and interacts with target tissues in the body. These features and other important issues related to the tiered approach to exposure-response assessment are discussed below. OSHA believes that there are a number of potential advantages to using a tiered risk assessment framework including opportunities to rely more heavily on peer-reviewed risk assessments already prepared by other Federal agencies.

b. Hazard Identification and Dose-Response Analysis in the Observed Range

Hazard identification is the first step in the Federal risk assessment framework as laid out by the National Research Council's 'red book' in 1983 (NRC, 1983; *Ex. #28*). In conducting a hazard identification, OSHA evaluates individual study quality and determines the weight of evidence from epidemiological, experimental, and supporting data. Study quality favors strong methodology, characterization of exposure during critical periods, adequate sample size/statistical power, and relevance to the workplace population. OSHA gives weight to both positive and negative studies according to study quality when the Agency evaluates the association between chemical agent and an adverse health effect. OSHA determines causality based on criteria developed by Bradford Hill (Hill, 1965; *Ex. #29,* Rothman & Greenland, 1998; *Ex. #30*). In its review of the available evidence, OSHA assesses the chemical's modes of action (MOA) and the key molecular, biological, pathological, and clinical endpoints that contribute to the health effects of concern.

The Mode of Action (MOA) is a sequence of key events and processes starting with the interaction of the agent with a molecular or cellular target(s) and proceeding through operational and anatomical changes that result in an adverse health effect(s) of concern. The key events are empirically measurable molecular or pathological endpoints and outcomes in experimental systems. These represent necessary precursor

steps or biologically-based markers along the progression to frank illness and injury.

MOA informs selection of appropriate toxicity-related endpoints and models for dose-response analysis. OSHA then conducts a dose-response analysis for critical health effects determined to be associated with a chemical, provided there are suitable data available. Dose-response analysis requires quantitative measures of both exposure and toxicity-related endpoints. OSHA gives preference to studies with relevant occupational routes that display a well-defined dose-related change in response with adequate power to detect effects at the exposure levels of interest. The Agency generally prefers high quality epidemiologic studies for dose-response analysis over experimental animal models, provided there is adequate exposure information and confounding factors are appropriately controlled. OSHA may only adopt standards for exposure to ''toxic materials and harmful physical agents'' that causes ''material impairment of health and loss of functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.'' OSH Act § 6(b)(5) (*Ex. #9*) Therefore, its dose-response analysis considers those biological endpoints and health outcomes that can lead to adverse physiological or clinical harm caused by continued exposure over a working lifetime. This includes key molecular and cellular biomarkers established as necessary precursor events along a critical disease pathway. It is important that the toxicity-related endpoints observed in experimental animals selected for dose-response analysis have relevance to humans and are not unique to the test species.

In the past, OSHA, for the most part, has undertaken an independent evaluation of the evidence in its identification of hazards and selection of critical studies and toxicity-related endpoints for dose-response analysis. However, other Federal agencies use the same risk assessment framework with similar hazard identification and dose-response selection procedures. EPA, ATSDR, NIOSH and others have active risk assessment programs and have recently evaluated many chemicals of interest to OSHA. These assessments undergo scientific peer review and are subject to public comment. The Agency is considering ways to reduce the time and resources needed to independently evaluate the available study data by placing greater reliance on the efforts of other credible scientific organizations. Although some organizations use their study evaluations to support non-occupational risk assessments, OSHA believes that, in most cases, these evaluations can be adapted to the occupational context.

Question IV.A.2: If there is no OSHA PEL for a particular substance used in your facility, does your company/firm develop and/or use internal occupational exposure limits (OELs)? If so, what is the basis and process for establishing the OEL? Do you use an authoritative source, or do you conduct a risk assessment? If so, what sources and risk assessment approaches are applied? What criteria do facilities/firms consider when deciding which authoritative source to use? For example, is rigorous scientific peer review of the OEL an important factor? Is transparency of how the OEL was developed important?

Question IV.A.3: OSHA is considering greater reliance on peer-reviewed toxicological evaluations by other Federal agencies, such as NIOSH, EPA, ATSDR, NIEHS and NTP for hazard identification and dose-response analysis in the observed range. What advantages and disadvantages would result from this approach and could it be used in support of the PEL update process?

c. Derivation of Low-End Toxicity Exposure (LETE)

An important aspect of the dose-response analysis is the determination of exposures that can result in adverse outcomes of interest. For most studies, response rates ranging from 1 to 10 percent represent the low end of the observed range. Epidemiologic studies generally are larger and can show a lower observed response rate than animal studies, which typically have fewer test subjects. EPA, ATSDR and EU REACH also derive an estimated dose at the low end of the observed range (*i.e.,* LETE) as part of their dose-response assessments. This dose is referred to as the POD ('point of departure') because it is used as a starting point for low dose extrapolation or the application of uncertainty factors as described above to derive toxicity values. EPA, ATSDR and EU REACH use the POD/extrapolation factor approach to determine Reference Concentrations (RfC), Minimal Risk Levels (MRL) and Derived No Effect Levels (DNELs), respectively. OSHA believes the LETE is an exposure where studies may have demonstrated significant risk. However, OSHA does not intend to use the LETE as the point of extrapolation for determining a ''safe'' exposure level in the manner used by the aforementioned agencies. OSHA may use the LETE in calculating an MOE to evaluate the need for low dose extrapolation as described in the next section.

Traditionally, either the Lowest Observed Adverse Effect Level (LOAEL) or No Observed Adverse Effect Levels (NOAEL) has served as easily obtainable LETE descriptors. More recently, the Benchmark Dose (BMD) methodology has increasingly been applied to derive an LETE. The BMD approach uses a standard set of empirical models to determine the dose associated with a pre-selected benchmark response (BMR) level. An example is the dose associated with a 10 percent incidence (*i.e.,* BMD_{10}) and the statistical lower confidence limit (*i.e.,* $BMDL_{10}$). Selection of an appropriate BMR considers biologic as well as statistical factors and a lower BMR is typically applied for clinically serious outcomes (*e.g.,* lung or heart disease) than for less serious adverse effects (*e.g.,* preclinical loss of neurological or pulmonary function). In some cases, more sophisticated models can be used in the LETE determination, based on physiologically-based toxicokinetics, toxicodynamics, or dosimetry models that relate the administered dose to a more toxicologically relevant dose metric at a biological target site, if sufficient data is available and the models are appropriately validated. This is discussed further below.

Question IV.A.4: OSHA is considering using the Point of Departure (POD) (*e.g.,* BMD, LOAEL, NOAEL), commonly employed by other authoritative organizations for carrying out non-cancer risk assessments as a suitable descriptor of the Low End Toxicity Exposure (LETE) level that represents a significant risk of harm. Is this an appropriate application of the POD by OSHA? Are there other exposure values that OSHA should consider for its LETE?

In many situations, the LETE must be adjusted to represent a typical worker exposure. The most common adjustments are to correct for the standard occupational exposure conditions of eight hours a day/five days a week and/or respiratory volume during work activity. OSHA and NIOSH have used a standard ventilation rate of 10 m^3 of air per 8-hour work shift for a typical worker undergoing light physical work activity.

Allometric scaling (*i.e.,* $BW^{3/4}$) is recommended by some Federal authorities when scaling animal doses to human equivalents to account for toxicokinetic differences in rates of absorption, metabolism, and excretion when more specific data is lacking. Allometric scaling refers to scaling

physiological rates and quantities to mass or volume of one animal species to another animal species. The relationship is generally dependent on body weight (BW), often in the form of $y=BW\alpha$ where y is the physiological measure and α is the scaling component. Many physiological and biochemical processes (such as heart rate, basal metabolic rate, and respiration rate have been found to have a scaling component of 0.75.

Allometric scaling is most applicable when the toxicologically relevant dose is a parent compound or stable metabolite whose absorption rate and clearance from the target site is controlled primarily by first order processes. Allometric scaling is less well suited for portal-of-entry effects or when toxicity is a consequence of a highly reactive compound or metabolite. Portal of entry refers to the tissue or organ of first contact between the biological system and the agent. This is nasal, respiratory tract and pulmonary tissues for inhalation; skin for dermal contact, and mouth and digestive tract for oral exposure.

In the case of respiratory tract effects from inhalation, EPA recommends adjusting inhalation doses based on generic dosimetry modeling that depends on the form of the chemical (*e.g.,* particle of gas) and site of toxicity (*e.g.,* portal of entry or systemic) (EPA, 1994; *Ex. #31*). For example, the human equivalent for a reactive gas that exerts its toxic effect on the respiratory tract is scaled based on animal to human differences in ventilation rate and regional surface area of the respiratory tract. On the other hand, the dosimetry model adjustment for an insoluble gas that exerts its effect in a tissue remote from the lung is scaled by species differences in the blood: gas partition coefficient. The generic dosimetry models can accommodate specific chemical data, if available. The models are only intended to account for human-to-animal differences in bioavailability and further allometric or extrapolation factors may be needed to account for species differences in metabolic activation and toxicodynamics (*i.e.,* target site sensitivity to an equivalent delivered dose).

Question IV.A.5: Several methodologies have been utilized to adjust critical study exposures to a worker equivalent under representative occupational exposure conditions including standard ventilation rates, allometric scaling, and toxicokinetic modeling. What are reasonable and acceptable methods to determine worker equivalent exposure concentrations, especially from studies in animals or other experimental systems?

The worker-adjusted LETE that is derived from dose-response analysis in the observed range should be regarded as a chemical exposure level that leads to significant risk of harm. In most cases, the LETE is expected to elicit a toxic response in 1 to 10 percent of the worker population. This approximates an excess risk of 10 to 100 cases of impairment per 1000 exposed workers over a duration that is typically less than a 45-year working life. This degree of risk would exceed the 1 per 1000 probability that OSHA historically regards as a clearly significant risk.

d. Margin of Exposure (MOE) as a Decision Tool for Low Dose Extrapolation

As discussed previously, OSHA's statutory and legal obligations dictate that PELs be set at the level that eliminates significant risk, if feasible, or if not, at the lowest feasible level. Therefore, Agency risk assessments are directed at determining significant risk at these feasible exposures. Because of the feasibility constraints, low dose extrapolation is not always needed to make the required risk findings. The OSHA significant risk orientation differs from other Federal Agencies, such as EPA and ATSDR. The risk-based EPA RfCs and ATSDR MRLs are intended as environmental exposure levels determined to be health protective without consideration of feasibility. NIOSH also develops workplace exposure limits. These recommended exposure limits (RELs) are based on risk evaluations using human or animal health effects data. The exposure levels that can be achieved by engineering controls and measured by analytical techniques are considered in the development of RELs, but the recommended levels are often below what OSHA regards as technologically feasible.

A MOE approach can assist in determining the need to extrapolate risk below the observed range. The appropriate MOE for use as a decision tool for low dose extrapolation is the LETE divided by an estimate of the lowest technologically feasible exposure (LTFE). A large MOE (*i.e.,* LETE/LTFE ratio) means the LTFE is considerably below exposures observed to cause adverse outcomes along a critical toxicity pathway. This situation would require low-dose risk extrapolation to determine whether technologically feasible exposures lead to significant risk. A small MOE means the LTFE estimate is reasonably close to the observed toxic exposures indicating the LTFE likely leads to significant risk of harm. In this situation, OSHA would set the PEL at the exposure level it determines to be feasible and the dose-response analysis in the observed range should be sufficient to support Agency significant risk findings.

There are several factors that OSHA would need to consider in order to find that the MOE is adequate to avoid low-dose risk extrapolation. These include the nature of the adverse outcome, the magnitude of the effect, the methodological designs and experimental models of the selected studies, the exposure metric associated with the outcome, and the exposure period over which the outcome was studied. OSHA may regard a larger MOE as acceptable to avoid the need for low-dose extrapolation for serious clinical effects than a less serious subclinical outcome. A larger MOE may also be found acceptable for irreversible health outcomes that continue to progress with continued exposure and respond poorly to treatment than reversible health outcomes that do not progress with further exposure. Health outcomes that relate to cumulative exposures would tolerate higher MOEs than similar outcomes unrelated to cumulative exposure, especially in short-term studies. In some instances, an adverse outcome observed in experimental animals would tolerate higher MOEs than the same response in a human study that more closely resembles the occupational situation.

Other Federal agencies apply the MOE approach as part of the risk assessment process. EPA has included MOE calculations in risk characterizations of environmental exposure scenarios to assist in risk management decisions (EPA, 2005; *Ex. #32*). The EU has also applied a very similar Margin of Safety analysis to characterize results of risk assessment conclusions (ECB, 2003; *Ex. #33*). In its report on the appropriate uses of risk assessment and risk management in federal regulatory programs, the Presidential Commission on Risk Assessment and Risk Management recommended MOE as an approach that provides a common metric for comparing health risks across different toxicities and public health programs (PCRARM, 1997; *Ex. #34*).

Question IV.A.6: OSHA is considering a Margin of Exposure approach that compares the LETE with the Lowest Technologically Feasible Exposure (LTFE) as a decision tool for low dose extrapolation. Is this a reasonable means of determining if further low dose extrapolation methods are needed to meet agency significant risk findings?

What other approaches should be considered?

e. Extrapolation Below the Observed Range

The last step in the tiered approach is extrapolation of risk below the observed range. This low-dose extrapolation would only be needed if the MOE is sufficiently high to warrant further dose-response analysis. This situation occurs when technologically feasible exposures are far below the LETE and quantitative estimates of risk could be highly informative in the determination of significant risk. As described in subsection A.1, OSHA has historically used probabilistic risk modeling to quantitatively estimate risks at exposure levels below the observed range. Depending on the nature of the exposure-response data, the Agency has relied on a wide range of different models that have included linear relative risk (*e.g.,* hexavalent chromium/lung cancer), logistic regression (*e.g.,* cadmium/kidney dysfunction), and physiologically-based pharmacokinetic (*e.g.,* methylene chloride/cancer) approaches.

Probabilistic risk models can require considerable time and resources to construct, parameterize, and statistically verify against appropriate study data, especially for a large number of chemical substances. As mentioned previously, several government authorities responsible for managing the risk to human populations posed by hazardous chemicals commonly use the computationally less complex uncertainty factor approach to extrapolate dose-response below the observed range. The uncertainty factors account for variability in response within the human population, uncertainty with regard to the differences between experimental animals and humans, and uncertainty associated with various other data inferences made in the assessment. For each of these considerations, a numerical value is assigned and the point of departure is divided by the product of all applied uncertainty factors. The result is an exposure level considered to be without appreciable risk. OSHA attempted to apply uncertainty factors in the 1989 Air Contaminants Rule to ensure that new PELs were set at levels that were sufficiently below exposures observed to cause health effects. The Eleventh Circuit ruled that OSHA had failed to show how uncertainty factors addressed the extent of risk posed by individual substances and that similarly, OSHA failed to explain the method it used to derive the safety factors. *Air Contaminants* 965 F.2d at 978.(*Ex. #8)* Since the court ruling, the uncertainty factor approach has undergone considerable refinement. The scientific considerations for applying individual factors have been carefully articulated by EPA and other scientific authorities in various guidance materials (EPA, 2002; *Ex. #35,* IPCS, 2005; *Ex. #36,* ECHA, 2012a; *Ex. #37*). For some factors under certain circumstances, it is being proposed that standard 'default' values can be replaced with 'data-driven' values (EPA, 2011; *Ex. #38*). However, the type and magnitude of the uncertainty factor employed for any individual substance still requires a degree of scientific judgment. The methodology does not provide quantitative exposure-specific estimates of risk, such as one in a thousand, that can readily be compared to the significant risk probabilities discussed in the *Benzene* decision.

The National Research Council's *Science and Decisions* report recently advocated a dose-response framework that provides quantitative risk estimates by applying distributions instead of 'single value' factors (NRC, 2009; *Ex. #24*). The critical extrapolation factors, such as species differences in toxic response at equivalent target doses and inter-individual variability in the human population are defined by lognormal distribution with an estimated standard deviation. This allows the human equivalent LETE to be derived in terms of a median and statistical lower confidence bound. The distributional nature of the analysis facilitates extrapolation in terms of a probabilistic projection of average and upper bound risk at specific exposures, such as X number of individuals projected to develop disease out of 1000 workers exposed to Z level of a toxic substance within some confidence level Y. The NRC report describes several different conceptual models with case examples and extrapolation factor distribution calculations (NRC, 2009; *Ex. #24*).

Question IV.A.7: Can the uncertainty factor methodology for extrapolating below the observed range for non-cancer effects be successfully adapted by OSHA to streamline its risk assessment process for the purpose of setting updated PELs? Why or why not? Are there advantages and disadvantages to applying extrapolation factor distributions rather than single uncertainty factor values? Please explain your reasoning.

3. Chemical Grouping for Risk Assessment

OSHA is also considering the use of one or more chemical grouping approaches to expedite the risk assessment process. In certain cases, it may be appropriate to extrapolate data about one chemical across a group or category of similar chemicals. These approaches are discussed below.

a. Background on Chemical Grouping

The term 'grouping' or 'chemical grouping' describes the general approach to assessing more than one chemical at the same time. It can include formation of a chemical category or identification of a chemical analogue (OECD, 2007; *Ex. #39*). Chemical categories or analogues can be based on the structural relationship between the chemicals being grouped.

Structure-activity relationships (SAR) are relationships between a compound's chemical structure and physicochemical properties and its biological effects (*e.g.,* cancer) on living systems. Structurally diverse chemicals can sometimes be grouped for risk analysis based on a common mechanism/mode of action or metabolic activation pathway (*i.e.,* mechanism/mode of action clustering). Endpoint information for one chemical is used to predict the same endpoint for another chemical, which is considered to be ''similar'' in some way (usually on the basis of structural similarity and similar properties and/or activities).

A chemical category is a group of chemicals whose physical-chemical, human health, environmental, toxicological, and/or environmental fate properties are likely to be similar or follow a regular pattern as a result of structural similarity, structural relationship, or other characteristic(s). A chemical category is selected based on the hypothesis that the properties of a series of chemicals with common features will show coherent trends in their physical-chemical properties, and more importantly, in their toxicological effects (OECD, 2007; *Ex. #39*).

The use of a category approach means that it is possible to identify chemical properties which are common to at least some members of the category. This approach provides a basis for establishing trends in properties across that category and extends the measured data (*e.g.,* toxicological endpoint) to similar untested chemicals.

In the category approach, not every chemical in a group needs to have exposure-response data in order to be evaluated. Rather, the overall data for the category as a whole must prove adequate to support a risk assessment.

The overall data set must allow for an assessment of risk for the compounds and adverse outcomes that lack adequate study. Chemicals may be grouped for risk assessment based on the following:

- Common functional group (*e.g.,* aldehyde, epoxide, ester, specific metal ion);
- Common constituents or chemical classes, similar carbon range numbers;
- Incremental and constant change across the category (*e.g.,* a chain-length category);
- The likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (*e.g.,* the metabolic pathway approach of examining related chemicals such as acid/ester/salt).

Within a chemical category, data gaps may be filled by read-across, trend analysis and Quantitative Structure-Activity Relationships (QSARs) and threshold of toxicological concern. In some cases, an effect can be present for some but not all members of the category. An example is the glycol ethers, where the lower carbon chain length members of the category indicate reproductive toxicity but the higher carbon chain length members of the category do not. In other cases, the category may show a consistent trend where the resulting potencies lead to different classifications (OECD, 2007; *Ex. #39*).

b. Methods of Gap Analysis and Filling

As a result of grouping chemicals based on similarities determined when employing the various techniques as described above, data gap filling in a chemical category can be carried out by applying one or more of the following procedures: read-across, trend analysis, quantitative (Q)SARs and threshold of toxicological concern (TTC).

i. Read-Across Method

The read-across approach uses endpoint information for one chemical (the source chemical) to predict the same endpoint for another chemical (the target chemical), which is considered to be ''similar'' in some way (usually on the basis of structural similarity or on the basis of the same mode or mechanisms of action). Read-across methods have been used to assess physicochemical properties and toxicity in a qualitative or quantitative manner. The main application for qualitative read-across is in hazard identification.

ii. Trend Analysis

Chemical category members are often related by a trend (*e.g.,* increasing, decreasing or constant) for any specific endpoint. The relationship of the categorical trend could be molecular mass, carbon chain length, or to some other physicochemical property.

The observation of a trend (increasing, decreasing or constant) in the experimental data for a given endpoint across chemicals can be used as the basis for interpolation and possibly also extrapolation to fill data gaps for chemicals with little to no data. Interpolation is the estimation of a value for a member using measured values from other members on ''both sides'' of that member within the defined category spectrum, whereas extrapolation refers to the estimation of a value for a member that is near or at the category boundary using measured values from internal category members (OECD, 2007; *Ex. #39*).

iii. QSAR

A Quantitative Structure-Activity Relationship (QSAR) is a quantitative relationship between a numerical measure of chemical structure, and/or a physicochemical property, and an effect/activity. QSARs use mathematical calculations to make predictions of effects/activities that are either on a continuous scale or on a categorical scale. ''Quantitative'' refers to the nature of the relationship between structurally related chemicals, not the endpoint being predicted. Most often QSARs have been used for determining aquatic toxicity or genotoxicity but can be used for evaluating other endpoints as well (OECD, 2007; *Ex. #39*).

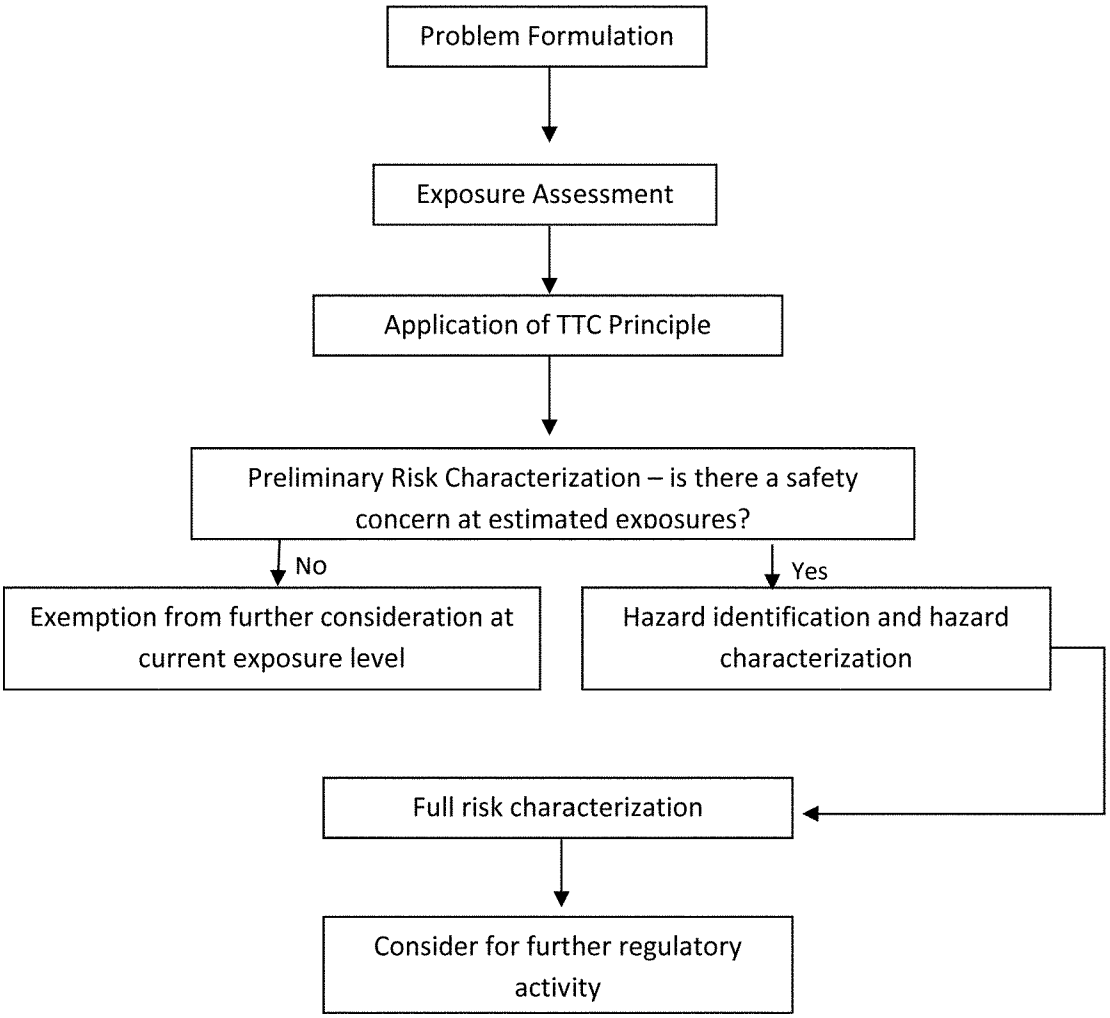
Question IV.A.8: Are QSAR, read-across, and trend analysis acceptable methods for developing risk assessments for a category of chemicals with similar structural alerts (chemical groupings known to be associated with a particular type of toxic effect, *e.g.,* mutagenicity) or other toxicologically-relevant physiochemical attributes? Why or why not? Are there other suitable approaches?

iv. Threshold of Toxicological Concern (TTC)

The Threshold of Toxicological Concern (TTC) refers to the establishment of an exposure level for a group of chemicals below which there would be no appreciable risk to human health. The original concept proposed that a low level of exposure with a negligible risk can be identified for many chemicals, including those of unknown toxicity, based on knowledge of their chemical structures. The TTC approach is a form of risk characterization in which uncertainties arising from the use of data on other compounds are balanced against the low level of exposure. The approach was initially developed by the FDA for migration of chemicals from consumer packaging into food products and used a single threshold value of 1.5μg/day (referred to as the threshold of regulation).

The TTC principle extends the concept used in setting acceptable daily allowable intakes (ADIs) by proposing that a de minimis value can be identified for chemicals with little to no toxicity data utilizing information from structurally related chemicals with known toxicities.

A decision tree can be developed to apply the TTC principle for risk assessment decisions:



For OSHA purposes the TTC approach could be adapted to develop an endpoint-specific LETE value for chemicals in a specific category where little to no toxicity data exist utilizing source chemicals within the category where toxicity data is available.

4. Use of Systems Biology and Other Emerging Test Data in Risk Assessment

Toxicity testing is undergoing transformation from an approach primarily based on pathological outcomes in experimental animal studies to a more predictive paradigm that characterizes critical molecular/cellular perturbations in toxicity pathways using *in vitro* test systems. The paradigm shift is being largely driven by the technological advances in molecular systems biology such as the use of high throughput screening (HTS) assays, new computational methods to predict chemical properties, and computer models able to associate molecular events with a biological response. The vision, strategies, and frameworks for applying the new toxicity data to risk-based decision making are laid out in landmark reports by the National Research Council (NRC, 2009; *Ex. #24,* NRC, 2007; *Ex. #25*). A collaborative Federal initiative known as ''Tox21'' has been established between the National Toxicology Program (NTP), the EPA Office of Research and Development, the NIH Chemical Genomics Center (NCGC), and the Food and Drug Administration (FDA) to collaborate on development, validation, and translation of innovative HTS methods to characterize key steps in toxicity pathways (NTP, 2013; *Ex. #40*). Tox21 has already screened over a 1000 compounds in more than 50 quantitative HTS assays that have been made available to the scientific community through publically accessible databases (*e.g.,* EPA ACToR, NTP CEBS). EPA has launched a program, known as ''NexGen'', to implement the NRC vision and advance the next generation of risk assessment (EPA, 2013b; *Ex. #41*). NexGen is a partnership among EPA, NTP, NCGC, AND FDA, along with ATSDR and California's EPA Office of Environmental Health Hazard Assessment. The objectives of NexGen are to pilot the new NRC risk assessment framework, refine existing bioinformatics systems, and develop specific prototype health risk assessments. These objectives are expected to be achieved through an iterative development process that includes discussion with scientists, risk managers, and stakeholders.

Question IV.A.9: How should OSHA utilize the new molecular-based toxicity data, high throughput and computer-based computational approaches being generated on many workplace chemicals and the updated NRC risk-based decision making framework to inform future Agency risk assessments?

B. Considerations for Technological Feasibility

Before adopting a particular regulatory alternative, the Agency must demonstrate that it is technologically feasible. As OSHA currently performs it, a technological feasibility analysis is often one of the most resource-intensive

aspects of the rulemaking process. The Agency must identify all of the industries that are potentially affected and compile the available information on current worker exposure and existing controls for each industry. On occasion, the best information available for technological feasibility analyses comes from sparse and incomplete data sets. Rather than rely exclusively on such variable information, OSHA is considering the use of exposure modeling, such as computational fluid dynamics (CFD) modeling, for a more complete picture of worker exposures and the potential effectiveness of different control strategies. Additionally, OSHA is looking at other sources of information, such as the REACH initiative from the European Union, that may help the Agency to better characterize industries or jobs where there is little to no data on worker exposures and control technologies.

1. Legal Background of Technological Feasibility

OSHA must demonstrate that a PEL, as well as any ancillary provisions, to the extend they are being adopted, are feasible. In general, OSHA determines that a regulatory alternative is technologically feasible when it has evidence that demonstrates the alternative is achievable in most operations most of the time. The Agency must also show that sampling and analytical methods can measure exposures at the proposed PEL within an acceptable degree of accuracy. OSHA makes these determinations in the technological feasibility analysis, which is made available to the public in the OSHA rulemaking docket.

2. Current Methodology of the Technological Feasibility Requirement

To develop its technological feasibility analysis, the Agency must first collect the information about the industries that are affected by a particular hazard, the sources of exposure, the frequency of the exposure, the number of workers exposed to various levels, what control measures or other efforts are being made to reduce exposure to the hazard, and what sampling and analytical methods are available.

This information is typically obtained from numerous sources including:

- Published literature,
- OSHA Special Emphasis Program (SEP) reports,
- NIOSH reports, such as health hazard evaluations (HHE), control technology (CT) assessments, surveys, recommendations for exposure control, and engineering control feasibility studies,
- Site visits, conducted by OSHA, NIOSH, or supporting contractors,
- Information from other stakeholders, such as federal and state agencies, labor organizations, industry associations, and consensus standards,
- Unpublished information, such as personal communications, meetings, and presentations, and
- OSHA Integrated Management Information System (IMIS) data.

With this information, OSHA creates profiles that identify the industries where exposures occur, what operations lead to exposures, and what engineering controls and work practices are being implemented to mitigate exposures. A technological feasibility analysis is typically organized by industry sector or group of sectors that performs a unique activity involving similar activities. OSHA identifies the operations that lead to exposures in all of these industries, and eventually determines the feasibility of a PEL by analyzing whether the PEL can be achieved in most operations most of the time, as an aggregate across all industries affected. OSHA has also utilized an application approach that evaluates the feasibility of controls for a specific type of process used across a number of industry sectors, such as welding, rather than on an industry-by-industry basis.

OSHA develops detailed descriptions of how the substance is used in different industries, the work activities during which workers are exposed, and the primary sources of exposure. The Agency also constructs exposure profiles for each industry, or by job category, based on operations performed. The Agency classifies workers by job categories within those industries, based on how similar work processes are, and to what extent similar engineering controls can be applied to control exposures in those processes.

Each exposure profile contains a list of affected job categories, summary statistics for each job category and subcategories (such as the mean, median, and range of exposures), and the distribution of worker exposures using increments based on the regulatory alternatives.

OSHA's technological feasibility analyses for PEL-setting standards have traditionally relied on full-shift, personal breathing zone (PBZ) samples to create exposure profiles. A PBZ sample is the best sample type to quantify the inhalation exposure of a worker. Area samples are typically not used to construct exposure profiles but are useful to characterize how much airborne contamination is present in a work environment and to evaluate the effectiveness of engineering and other process control measures.

Exposure profiles are used to establish the baseline exposure conditions for every job category in affected industries. Baseline conditions are developed to allow the Agency to estimate the extent to which additional controls will be required to achieve a level specified by a regulatory alternative.

Next, the technological feasibility analysis describes the additional controls necessary to achieve the regulatory alternatives. OSHA relies on its traditional hierarchy of controls when demonstrating the feasibility of control technology. The traditional hierarchy of controls includes, in order of preference: Substitution, local exhaust ventilation, dust suppression, process enclosures, work practices, and housekeeping. OSHA considers use of personal protective equipment, such as respirators, to be is the least effective method for controlling employee exposure, and therefore, personal protective equipment is considered only for limited situations in which all feasible engineering controls have been implemented, but do not effectively reduce exposure to below the permissible exposure limit. To identify what additional controls are feasible, the Agency conducts a detailed investigation of the controls used in different industries based primarily on case studies.

OSHA develops preliminary conclusions regarding feasibility of regulatory alternatives, by identifying the lowest levels of exposure that are technologically feasible in workplaces. To determine whether an alternative is feasible throughout the spectrum of affected industries, OSHA studies whether the regulatory alternative is achievable in most operations most of the time by a typical firm. OSHA may also determine whether a specific process used across a number of different industries can be effectively controlled.

3. Role of Exposure Modeling in Technological Feasibility

In many situations, the Agency has found it difficult to develop comprehensive exposure profiles and determine additional controls because of limitations associated with the available exposure data. These information gaps could be filled by incorporating exposure modeling into the technological feasibility process. The limitations associated with the data collected include:

- *Limited number of exposure samples:* On occasions, an exposure

profile for a job category may be built on a limited number of full-shift exposure samples, and the Agency has to judge whether the samples available are representative of the actual exposure distribution for that industry.

• *Limit of Detection (LOD) issues:* Because only a few exposure samples may be available for a job category, the analysis may include samples reported as ''less than'' values, high LODs, or adjusted LOD values. This causes inconsistency in the use of LOD samples and may cause the Agency to under- or over-estimate the actual exposure distribution.

• *Lack of information on controls associated with data:* Information regarding working conditions and control strategies associated with exposure samples may not be available. This makes it difficult for the Agency to determine the impact of the control strategies for various sources of exposure. Additionally, it is common that the data does not include information about the exact nature of the task performed during the sampling period. Sometimes, samples may not exactly correspond to the job category to which OSHA assigns it in the analysis because the job activities performed are not adequately described.

• *Limitations of traditional industrial hygiene sampling:* Traditional industrial hygiene practices require a ''before and after'' data set to gauge the effectiveness of control strategies implemented, and changes that occur in the working environment during the sampling periods. The exact impact of control strategies and environmental conditions cannot be determined easily with only one set of samples obtained at a discrete moment in time. It is often the case that OSHA does not have the luxury of ''before and after'' data sets and must determine how the sample set fits into the exposure profile.

• *IMIS data limitations:* Since the Agency may lack exposure data for a particular job category or operation, it sometimes relies on IMIS data. OSHA does not usually rely on IMIS data in its exposure profiles unless there are no other exposure data available because the IMIS data can have some significant limitations, which include the following:

○ Insufficient information to determine if a hazard is present in the work area in significant amounts as to be relevant for an exposure profile. For example, an analyst cannot tell from the information available in the IMIS database if a sample was targeted for the hazard in question, or if it was part of a larger metal screening process (if the hazard is a metal), which typically includes up to 16 different metals whether they are thought to be present in the sampling environment or not.

○ Use of SIC codes in historic IMIS data, which do not translate directly into the NAICS codes currently used in the analyses.

○ There is no information in the database on the end product being developed, the action performed to produce it, or the materials being used when the sample is taken. This limits the interpretation of the data, since an analyst is not able to attribute the exposure to any particular practice or process, and cannot recommend engineering controls.

Generally, OSHA has had the most success using IMIS data to identify and collect enforcement case files for further review. Case files from OSHA inspections contain more detailed information on worker activities and exposure controls observed at the time an exposure sample is taken. Thus, use of case files to a large extent mitigates the limitations of using IMIS data.

For most health standards, OSHA does not have the resources to conduct site visits to obtain the necessary exposure information at firms that are representative of all the affected industries. In an effort to develop more robust exposure profiles, the Agency is considering the use of exposure modeling, such as computational fluid dynamics (CFD) modeling, to complement the exposure information that is already available from literature, site visits, NIOSH and similar field investigations, and employer-provided data. This technique would potentially allow OSHA to better estimate workplace exposures in those environments were data are limited.

Question IV.B.1: OSHA described how it obtains information necessary to conduct its industry profiles. Are there additional or better sources of information on the industries where exposures are likely, the numbers of workers and current exposure levels that OSHA could use?

a. Computational Fluid Dynamics Modeling To Predict Workplace Exposures

OSHA is considering the use of computational fluid dynamics (CFD) to model workplace exposure. CFD is a discipline of fluid mechanics that uses computer modeling to solve complex problems involving fluid flows. Fluid flow is the physical behavior of fluids, either liquids or gases, and it is represented by systems of partial differential equations that describe conservation of energy, mass, and momentum. For some physical phenomena, such as the laminar flow of a fluid through a cylindrical pipe, these equations can be solved mathematically. Such solutions describe how a fluid will move through the specified area, or geometry, as a function of time. For more complex physical phenomena, such as turbulent flow of a fluid through a complex geometry, numerical approaches are used to solve the governing differential equations. As such, CFD modeling uses mathematical models and numerical methods to determine how fluids will behave according to a particular set of variables and parameters. A mathematical model simulates the physical phenomena under consideration (*i.e.* governing equations of energy, mass, and momentum) and, in turn, a numerical method solves that model. Overall, CFD modeling enables scientists and engineers to perform computer simulations in order to make better qualitative and quantitative predictions of fluid flows.

Some modeling techniques, such as CFD, allow a user to create a virtual geometry to simulate actual work environments using appropriate mathematical models and computational methods. The solutions predict exposures at any given time and in any point in the space of the geometry established. A model developed with this technique allows the user to evaluate exposures in a worker's personal breathing zone and identify areas in the work space that present high concentrations of the contaminant. Because the exposure concentration can be solved as a function of time, the user can observe how concentration increases or decreases with time or other changes in the model input parameters. This allows the user to consider administrative controls such as limiting the time of the operation, the quantity of material emitted by the process, or determining how long after an operation a worker can safely enter a previously contaminated area. In some cases, work tasks and processes that are time-varying can be communicated to the CFD model through time-varying boundary conditions.

Models require a defined geometry (*i.e.,* work space), and this step in the model building may be resource intensive. To construct geometries of complex work environments, OSHA would need to gather the necessary information to model the work environment. This includes taking measurements of the work area, machinery, engineering control specifications (*e.g.,* exhaust face velocities, spray systems flow rates),

and any other objects or activities that may affect the air flow in the area of interest. Moreover, gathering site-specific information for building CFD models can be integrated with traditional industrial hygiene survey activities. OSHA is interested in identifying ways to reduce the time and money that may be spent recreating work environments. One alternative is to import facility layouts in an electronic format (such as CAD) into the modeling software. If an establishment has its facility layout in this format, then the model designer would not have to take physical measurements and recreate the work area by 3–D modeling.

Question IV.B.2: In cases where there is no exposure information available, to what degree should OSHA rely on modeling results to develop exposure profiles and feasible control strategies? Please explain why or why not.

Question IV.B.3: What partnerships should OSHA seek to obtain information required to most efficiently construct models of work environments? More specifically, how should OSHA select facility layouts to model that are representative of typical work environments in a particular industry? Note that the considerations should include variables such as work area dimensions, production volumes and ventilation rates in order to develop models for both large and small scale operations.

Models must undergo validation and testing to determine if they provide an accurate prediction of the physical phenomenon under consideration, or in this case, the concentrations of air contaminants to which workers could be potentially exposed. Sensitivity analyses can be used to determine if model outputs are consistent given minor changes to grid cell size and time step duration. Grid cell size refers to the division of space according to nodes, and time step refers to the value attributed to the time variable to numerically solve the equations with reference to the nodes. Another method for model evaluation is the comparison between the solutions of different models to the same problem in that a similarity of findings across multiple CFD models would provide greater confidence in the results. Arguably, the best performance evaluation is the comparison of model results to those of a field experiment that simulates on different scales the actual work environment.

This method of predicting workplace exposures has some potential advantages over traditional industrial hygiene sampling methods. Patankar (1980; *Ex. #42*) explains some of the advantages of theoretical calculations, in a general sense, to predict heat transfer and fluid flow processes. Some of these are:

- *Low Cost:* In many current and future applications, the cost of a computational method may be lower than the corresponding sampling cost. As mentioned above, the most resource-consuming aspect of solid modeling is simulating the geometry that resembles actual physical space of work environments.
- *Speed:* A numerical solution to predict exposures can be obtained very easily in a day. A user could manipulate different configurations regarding worker positioning and engineering controls to find an optimal control strategy.
- *Complete information:* A computer solution provides the values of all relevant variables throughout the domain of interest. These variables cover fluid flow patterns, areas in the geometry with highest concentrations of contamination, exposure values at any point in the geometry, time profile of contamination, and exposure results based on different control configurations. Traditional industrial hygiene sampling does not allow for this level of analysis as it measures results based on a particular work environment, and it cannot distinguish how each independent variable (*e.g.,* changes in the workplace during sampling) affects the exposure result.
- *Ability to simulate realistic conditions:* A computer solution can accommodate any environmental condition and the values for all variables that affect the solution can be easily modified to fit a particular scenario.

Patankar (1980; *Ex. #42*) also discusses the disadvantages of theoretical predictions to address heat transfer and fluid flow processes, and they are applicable to exposure modeling. The solutions obtained depend on the mathematical model used to simulate the situation, the value of the input parameters, and the numerical method used to obtain a solution. As Patankar notes, ''a perfectly satisfactory numerical technique can produce worthless results if an inadequate mathematical model is employed''. This is why it is imperative that the mathematical model chosen actually resembles the physical phenomena under consideration.

The Agency also realizes that even if an appropriate mathematical model and numerical method are obtained to describe contamination in a workplace, the exposure modeling approach may prove to be more resource-intensive than traditional industrial hygiene sampling for work environments with complex geometries. In these situations, OSHA would have to develop a site visit protocol for gathering dimensions of the work environment of interest. The information to be collected includes the dimensions of the physical space, the ventilation system that affects airflow patterns, and other details (such as location and size of windows, doors, and large obstructions).

Despite these limitations, modeling promises to provide significant advantages that could help OSHA construct more robust technological feasibility analyses while reducing the considerable amount of resources the Agency already expends on them. In addition to CFD modeling, the Agency will continue to investigate other exposure modeling techniques and their applicability in the rulemaking process.

Question IV.B.4: Should OSHA use only models that have been validated? If so, what criteria for model validation should be employed?

Question IV.B.5: What exposure models are you aware of that can be useful for predicting workplace exposures and help OSHA create exposure profiles and in what circumstances?

At this time, OSHA is primarily examining the possibility of incorporating CFD models to indoor work operations. Most general industry and some construction operations are performed indoors. As the Agency conducts more research on the applicability of CFD models to predict workplace exposures, outdoor models will also be considered. As such, OSHA is interested in obtaining input from parties experienced in these models.

Question IV.B.6: Should OSHA consider CFD models primarily for indoor operations, outdoor operations, or both? What limitations exist with these two different types of models?

Various U.S. federal agencies have used CFD modeling for projects related to indoor air quality and/or occupational health and safety. Preliminary research indicates that this CFD modeling work has been performed mostly for academic and research purposes. There is little information available discussing the use of CFD modeling for the purposes of litigation and/or regulatory decision-making.

NIOSH has used CFD on a variety of internal research initiatives that involve evaluating and controlling airborne exposures. Among other projects, NIOSH has used CFD modeling to:

- Evaluate potential exposure concentrations to hexavalent chromium (CrVI), hexamethylene diisocyanate

(HDI), methyl isobutyl ketone (MIBK), and others with different ventilation control configurations during spray painting operations at a Navy aircraft paint hangar. In this study, NIOSH also tested and validated the predictive value of CFD modelling against methods of physical sampling by conducting workplace air sampling and comparing with model results. The project was performed with assistance from the Naval Facilities Engineering Command (NAVFAC) and the Navy Medical Center San Diego (NMCSD) (NIOSH, 2011a; *Ex. #43*),

- Study the effectiveness of ventilation systems for controlling Tuberculosis (NIOSH, 2010; *Ex. #44*),
- Evaluate emission controls for mail processing and handling facilities (NIOSH, 2010; *Ex. #44*),
- Better understand the role airflow and ventilation play in disease transmission in commercial aircraft cabins (NIOSH, 2010; *Ex. #44*),
- Simulate different air sampling methods to better understand how sampling methods can assess exposure (NIOSH, 2010; *Ex. #44*), and
- Help better understand the effectiveness of various forms of exposure control technologies in the manufacturing and transportation, warehousing, and utilities in the National Occupational Research Agenda (NORA) Sectors (NIOSH, 2011b; *Ex. #45*).

Additionally, NIOSH has also used CFD models in mine safety research:

- NIOSH conducted a CFD study to model the potential for spontaneous heating in particular areas of underground coal mines (Yuan, L. et al., 2006; *Ex. #46*). The purpose of the study was to provide insights into the optimization of ventilation systems for underground coal mines that face both methane control and spontaneous combustion issues.
- NIOSH looked at the rate of flame spread along combustible materials in a ventilated underground mine entry. CFD models were used to estimate the flame spreading rates of a mine fire (Edwards, J. C., and Hwang, C. C., 2006; *Ex. #47*).
- NIOSH has also used CFD modeling to model inert gas injection and oxygen depletion in sealed areas of underground mines (Trevits, M. A., et al., 2010; ; *Ex. #48*). CFD simulations were created to model inert gas injections that aim to eliminate explosive atmospheres that form in sealed mine areas. The CFD model was able to quantify oxygen depletion and gas leakage rates of the sealed area.

EPA has conducted a substantial amount of work using CFD modeling to assess outdoor air quality. However there is little information available on EPA projects that have used CFD to evaluate indoor air quality.

As part of the Labs21 program, EPA, in conjunction with the Department of Energy, has published a guidance document for optimization of laboratory ventilation rates (EPA & DOE, 2008; *Ex #49*). The guidance is geared towards architects, engineers, and facilities managers, in order to provide information about technologies and practices to use in designing, constructing, and operating safe, sustainable, high-performance laboratories. EPA advocates the use of CFD simulations to determine the airflow characteristics of a laboratory space in order to improve ventilation systems and increase safety and energy efficiency.

The Building and Fire Research Laboratory of National Institute of Standards and Technology (NIST) developed a CFD model to simulate the transport of smoke and hot gases during a fire in an enclosed space (NIST, 1997; *Ex. #50*). The results of the study and an extensive literature review indicated to NIST that CFD can have significant benefits in the study of indoor air quality and ventilation. The report resulting from this study provides a thorough description of CFD and provides recommendations for future directions in CFD research.

The Building and Fire Research Laboratory of NIST has also used CFD to model the effects of outdoor gas generator use on the air concentrations of carbon monoxide inside nearby buildings (NIST, 2009; *Ex. #51*). Using CONTAM (a mathematical indoor air quality model), coupled with CFD simulations, the researchers were able to determine factors (*e.g.,* generator positioning, wind direction) that contributed to elevated carbon monoxide accumulation in the building.

As OSHA continues to explore the option of incorporating CFD modeling into its technological feasibility analyses, the Agency will conduct further research on existing models.

b. The Potential Role of REACH in Technological Feasibility

Similar to the evaluation of chemical substances by the European Chemicals Agency (ECHA) and the European Commission before making a decision to ban or restrict the use of a substance, OSHA must evaluate information on health effects, exposure levels, and existing controls before setting a new or revised PEL. However, ECHA requires chemical manufacturers to generate the information evaluated by government decision-makers, while in the U.S., OSHA itself is responsible for generating, researching, and evaluating the relevant information.

As explained in more detail above, OSHA creates industry profiles to evaluate the technological feasibility of a standard. The objective of these profiles is to estimate the number of workers potentially exposed to occupational hazards. OSHA relies on information from numerous sources including the U.S. EPA, U.S. DOL, U.S. Census Bureau, NIOSH, scientific publications, and site visits to identify specific industries where workers are potentially exposed to hazards.

Acquiring data from these sources is straightforward and usually achieved through standard procedures. However, these sources often contain data gaps or inconclusive information. Thus, new sources of information are needed to fill existing data gaps and strengthen OSHA's analyses.

Since similar types of data are currently being developed and submitted by manufacturers and importers under REACH, this information could provide an additional reference source for OSHA to utilize. The incorporation of REACH data into OSHA's technological feasibility analyses could greatly assist the Agency in creating a more exhaustive, thorough, and complete analysis. The information developed during the REACH registration process could help OSHA better understand the industries, uses, processes, and products in which a chemical of concern is used, gain knowledge about the risk management measures and controls currently in place, and develop scenarios where exposure may be greatest. Exposure information generated by manufacturers in a chemical safety assessment could be valuable for completing exposure profiles on chemicals where current references for field sampling analytical data are limited. In addition, utilizing information presented in exposure scenarios that describe the conditions under which a chemical can be used safely (*i.e.,* risk management measures and operating conditions) could provide insight on currently employed industry control methods and their effectiveness.

While the benefits of incorporating REACH data into OSHA's technological feasibility analyses seems promising, challenges such as data access and data validity have been identified as potential drawbacks. Despite provisions under REACH that require the public availability of data and the sharing of data with other government agencies, the European Chemicals Agency, which maintains the REACH databases, has not

yet made some of the information available, including information generated for and compiled in the chemical safety assessment. Additionally, some manufacturers and importers may be prohibited from sharing the data generated for REACH directly with other entities for non-REACH purposes due to agreements made among the members of groups organized under REACH to more efficiently share the information needed for the registration of a chemical.

Question IV.B.7: How can exposure information in REACH be incorporated into OSHA's technological feasibility analysis?

c. Technological Feasibility Analysis With a Focus on Industries With Highest Exposures

OSHA's technological feasibility analysis is one of the most resource-intensive parts of the rulemaking process. OSHA typically analyzes exposures in all industries and job categories within those industries that show potential for exposures and determine whether a proposed exposure limit can be achieved in most operations most of the time. These can range from industries that are constantly experiencing exposures in most job categories above an existing PEL or the regulatory alternatives, to industries where only a few job categories have shown elevated exposures. OSHA has also utilized an application approach in which it analyzed exposure associated with a specific process across a number of different industries.

The Agency is investigating whether it is appropriate to focus future technological feasibility analyses only on job categories that have the highest exposures. An analysis performed in this manner may reduce the amount of time and money OSHA has to expend to prove feasibility. In many cases the control methods applicable for one industry may also be effective in reducing exposures in other industries. By determining the additional engineering controls and work practices necessary to reduce the most elevated exposures to a level specified by a regulatory alternative, the Agency could propose that similar control strategies (wherever applicable) would also be effective in reducing lesser exposures to that same level. In other words, by making feasibility findings in the most problematic industries, OSHA would argue that all other industries would also be able to comply with a regulatory alternative. A related possibility is for OSHA to make a feasibility determination based on enforcement activities of the proposed or lower PEL in other geographic jurisdictions, *e.g.,* other states.

Question IV.B.8: To what extent and in what circumstances should OSHA argue that feasibility for a regulatory alternative can be established by proving the feasibility of reducing the highest exposures to the level proposed by that regulatory alternative?

Question IV.B.9: To what extent and in what circumstances can OSHA argue that feasibility for a regulatory alternative can be established by the enforcement of a lower PEL [*e.g.,* the 1989 PEL (See Appendix B)] by an individual state or states?

Question IV.B.10: What are the appropriate criteria that OSHA should use to assess whether control strategies implemented in a process from one industry are applicable to a process from another industry (*e.g.,* similarity of chemicals, type, extent and duration of exposures, similar uses)?

Question IV.B.11: Regardless of the industries involved, are there criteria that OSHA should use to show that control strategies implemented in a process from one operation are applicable to a process from another operation? Please explain.

The Agency realizes that analyses performed in this manner may have some implications for smaller firms that may find it harder to implement resource intensive control strategies than larger firms. Additionally, the control strategies from the most problematic industries may not be similar to those that may be needed for industries with lower exposures because the processes and sources of exposure require different control methods.

Question IV.B.12: How should OSHA take into consideration the size of a business of facility when determining technological feasibility?

C. Economic Feasibility in Health Standards

The purpose of this section is (1) to discuss how and why OSHA currently conducts its economic feasibility analysis of health standards, and (2) to examine approaches to economic feasibility that might involve less time and fewer resources.

1. OSHA's Current Approach to Economic Feasibility

The Agency's existing approach to economic feasibility rests directly on relevant language in the OSH Act, as interpreted by the courts, requiring OSHA to establish that new standards are economically feasible. OSHA also conducts economic analysis of its regulations in compliance with other legislation and as a result of executive orders that require analysis of the benefits and costs of a regulation as a whole, and in the case of the Regulatory Flexibility Act, some estimate of the economic impacts on small entities. However, the degree of industry detail provided in OSHA's economic analyses is primarily a function of judicial interpretation of the economic feasibility requirements of the OSH Act. The development of the law on economic feasibility is discussed in detail in Section III. Below we discuss potential alternatives to current methods of economic feasibility analysis, and then follow with a brief discussion on how the other analytical requirements OSHA is required to meet might be satisfied.

As guided by the courts, OSHA develops economic feasibility analyses that cover every affected industry and process. OSHA has not always taken this position. For example, in its economic and technological feasibility analysis of benzene, OSHA examined only industries believed to be the worst in terms of significant exposure to benzene. Since then, however, OSHA has attempted to cover all affected industries in its feasibility analysis.

The courts have suggested that the economic feasibility analysis must be reasonably detailed. In the *Air Contaminants* case, the court said:

> Indeed, it would seem particularly important not to aggregate disparate industries when making a showing of economic feasibility . . . [R]eliance on such tools as average estimates of cost can be extremely misleading in assessing the impact of particular standards on individual industries. *AFL–CIO* v. *OSHA,* 965 F.2d 962, 982 (11th Cir. 1992) *(''Air Contaminants'').* *(Ex. #8)*

However, the court added:

> We are not foreclosing the possibility that OSHA could properly find and explain that certain impacts and standards do apply to entire sectors of an industry. Two-digit SICs could be appropriate, but only if coupled with a showing that there are no disproportionately affected industries within the group. *Air Contaminants,* 965 F.2d at 982 n.28

In the hexavalent chromium case, *Public Citizen Health Research Group* v. *United States Dep't of Labor,* 557 F.3d 165, 178 (3d Cir. 2009; Ex. #14), the court recognized that OSHA had the flexibility to demonstrate technological feasibility on a process or activity rather than industry-by-industry basis, if the processes or activities are sufficiently similar from industry to industry. The court, however, did not address the question of whether the same flexibility applies to economic feasibility. OSHA, especially in health standards, has tried

to provide the most detailed analysis of industries and processes that resources permit. For most recent health standards, this has meant the use of the lowest level industry codes for which industry data are available, and where more than one process is used in an industry, consideration of each process separately. Further, in order to assure that a regulation does not alter the competitive structure of an industry, OSHA normally analyses three size classes of employer within each industry: All establishments, small firms as defined by SBA, and small firms with fewer than twenty employees (always smaller than the SBA definitions). For the typical OSHA substance-specific health standard, OSHA analyses each of the controls for each of the many processes in which the substance might appear, and then of each industry in which any process might appear, and then of three sizes of establishment within the industry. Finally, OSHA examines the varying levels of exposure and controls within an industry and develops analyses that reflect these differences within an industry. In terms of the form of the analysis, OSHA has followed the advice of the D.C. Circuit to ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.'' *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1272 (D.C. Cir. 1980; Ex. #12) (''*Lead I*'').

In response to this guidance, OSHA develops detailed estimates of the costs of a health standard for each affected industry, and by the three size categories of establishment. The result is that the economic analyses of health standards routinely contain a series of tables showing costs for each industry by multiple size classes of firms within the industry, and sometimes for more than one process per industry. Each entry in these tables is documented by detailed explanations of how the costs were estimated for each industry and size class and level of exposure.

OSHA then makes a determination for each industry whether or not these costs are likely to threaten the existence or competitive structure of that industry. In order to do this, OSHA first constructs a ''screening analysis'' for each industry. For the purposes of this screening analysis, OSHA combines its estimates on the costs per establishment of various sizes with statistical data on the profits and revenues of the affected establishment sizes, and then calculates costs as a percentage of profits and revenues. For most industries, the costs in comparison to revenues and profits are so small that, in OSHA's view, no reasonable person could think that the costs could possibly be expected to threaten the existence or competitive structure of an industry. Where the costs are not this small, OSHA conducts a variety of further economic analysis, depending on the economic situation, nature of the costs, the affected industry, and the economic data available.

This basic approach to economic feasibility analysis has been used for many health standards, and the approach has generally been successful in assuring that OSHA standards are economically feasible. In the PELs rulemaking, where OSHA tried a more general approach, the court found the level of detail inadequate. Similarly, OSHA has encountered problems when the Agency did not have an adequate level of detail with respect to the exposure profile and the technological feasibility analysis, such as for dry-color formulators of cadmium pigments. OSHA's eight lookback studies, conducted under both Sections 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866, have not found any instance in which subsequent study showed that a standard had threatened the existence of or brought about massive dislocation within an industry.

OSHA can reasonably say that it has found a methodology such that the Agency's determinations of economic feasibility have both been considered adequate by the courts and proven to be accurate in determining regulations to be feasible when re-evaluated by retrospective analysis. However, the resulting methodology is extremely resource intensive and time-consuming because OSHA always has to make detailed cost estimates and provide detailed statistical data for every single process and industry affected. For this reason, OSHA wants to consider whether there may be methods that can short-cut this process and still meet all of OSHA's legal requirements.

The remainder of this section examines two kinds of alternative approaches to accelerating the process and reducing the resources needed to produce health standards. One kind of alternative involves formulating health standards differently. The second kind involves different kinds of analysis OSHA might perform.

2. Alternative Approaches to Formulating Health Standards That Might Accelerate the Economic Feasibility Analysis

One approach to simplifying, speeding up, and making the development of standards less resource intensive would be to have the standards themselves address health issues in a way that involves less analysis for any given standard. Health standards can be analyzed faster to the extent that there are fewer processes and/or fewer industries to analyze. It would be less time consuming for OSHA to analyze a health standard for a single process rather than a single substance that is found in dozens of processes. OSHA already has a variety of process-oriented standards that partially address health hazards in such areas as abrasive blasting, welding, and electroplating. Control banding also represents an approach that, following the hazard assessment, examines controls for specific processes. In control banding, the hazards are generic, but the controls are process specific. Process-oriented approaches would be most useful for processes widely used in a variety of settings—abrasive blasting, degreasing, welding, etc. Industry-by-industry economic feasibility analysis for a process-oriented approach would be enormously simplified by the fact the controls and their costs would be very similar across industries. As a result, OSHA could develop more detailed and more secure cost estimates, with full opportunities for a variety of affected parties to comment on those estimates. This approach might also serve to greatly simplify the technological feasibility analysis. On the other hand, since process-oriented standards commonly involve multiple substances, risk assessment issues might be more complex.

A related approach to speeding up at least portions of substance specific health standards might be to regulate a single substance process by process in multiple rulemakings—for example, regulate exposures to hexavalent chromium in electroplating, then in welding, and then painting. By producing process standards in this manner, rather than waiting until analyses of all processes and industries is completed, OSHA could potentially address the most severe exposures much more rapidly. This approach could also allow OSHA to ignore processes where the exposures are likely to be small and the chance of exceeding a PEL minimal. Though this approach might result in portions of a substance-specific standard being produced more quickly, the approach would probably require more resources for multiple hearings and docket analyses. A major disadvantage of this approach is that it would result in the possibility that workers in industries not yet regulated

would have to endure exposures higher than those in regulated industries. Another disadvantage might be that the risk assessment would be subject to multiple public hearings as each industry or process was regulated.

3. Alternative Analytic Approaches to Economic Feasibility of Health Standards

A different approach to producing less resource-intensive and time-consuming economic feasibility analyses would be to re-examine whether OSHA's basic approach of estimating the costs of each process, industry, size class, and possible level of control is really necessary in all cases given how the courts have defined economic feasibility. The key to meeting the legal requirements is to return to the concept of economic feasibility. In the *Lead I* decision, the court stated:

> A standard is feasible if it does not threaten ''massive dislocation'' to . . . or imperil the existence of the industry. No matter how initially frightening the projected . . . costs of compliance appear, a court must examine those costs in relation to the financial health and profitability of the industry and the likely effect of such costs on unit consumer prices. More specifically . . . the practical question is whether the standard threatens the competitive stability of an industry. *Lead I,* 647 F.2d at 1265 (citations omitted). (Ex. #12)

As the court recognized, this is a strong criterion. In the real world, industries are rarely eliminated or have their competitive structure radically altered for reasons related to changes in their costs, and it is changes in costs that courts recognized as the principle reason a regulation might not be economically feasible. Radical changes in industries tend to come from two major causes. Most are the result of changes in demand such that the public is no longer interested in the product or service an industry provides, for such reasons as technological obsolescence or the existence of better substitutes. Some radical changes in industries are the result of foreign competition. However, foreign competition applies largely, in an OSHA context, to manufacturing, but not to construction, utilities, domestic transportation, or most services that OSHA regulates.

OSHA is not aware of any instance in which an OSHA regulation eliminated or altered the competitive structure of an industry—though in some cases, a combination of liability-based concerns, environmental regulations, and OSHA regulation may have radically altered the use of a product. For example, asbestos is not used in many applications where it was once commonplace. Benzidine-based dyes have disappeared from the U.S. marketplace. However, these cases had no effect on the viability of user industries or their employment. Insulation contractors still install insulation—it just no longer contains asbestos. Dyers continue to dye textiles and leather all the colors benzidene-based dyes imparted, but without using benzidene-based dyes. The chief effect has been substitution away from a substance. This has resulted in serious economic impacts on a limited number of producers of the substance but little economic impact on the thousands of users of the substance who simply found a substitute. It would seem that such substitution away from a substance is not the kind of economic change that would make a regulation economically infeasible.

OSHA might be able to place major emphasis on evidence that a significant portion of an industry is already meeting a standard. Such evidence is an obvious indication that a standard is both technologically and economically feasible for that industry. After all, the actual fact that a majority of employers of all sizes in an industry is meeting a standard, while remaining viable, should be more convincing than a set of cost estimates in an economic analysis predicting that employers in a given industry could meet the standard. Actual empirical evidence of a proposition is normally considered superior to theoretical evidence for a proposition. There are several reasons why many or most employers in an industry may already meet a standard—these include ease of meeting the standard, industry consensus standards, and concern about liability.

Similarly, the fact that a state or other jurisdiction has already implemented a requirement and that firms within the state are generally following the requirement would represent very strong evidence that a requirement is economically and technologically feasible. For example, twenty-two states currently operate their own OSHA programs that cover both private sector and State and local government employees, and five states cover public employees only. Of the twenty-two states that cover both private and public sector employees, five states (South Carolina, Minnesota, Tennessee, Vermont and Washington) are still enforcing the 1989 PELs, and did not revert to the less protective PELs when the Court remanded the *Air Contaminants* rule. *(Ex. #8)* Michigan is also enforcing the 1989 PELs in general industry, but not in construction. Three states (Connecticut, Illinois, and New York) are enforcing the 1989 PELs in the public sector only. California enforces its own PELs which in many cases are substantially lower than OSHA's. Situations in which most firms in a state meet a potential requirement of a standard are particularly convincing because they show that employers are not only able to carry out the requirement, but can do so even in competition with employers who are not required to meet such a requirement.

Nevertheless, OSHA is aware that some care must be taken with evidence that all or most firms in an industry or in an industry within a state meet a requirement. It is particularly important to determine whether those who do not meet the requirement might require fundamentally different controls, have different costs, or operate in a different market in spite of being in the same statistical industry. Consider a standard addressing a specific metal. Most firms in an industry may find the standard easy to meet because they only use the metal in alloys that call for a very small percentage of the metal. However, those firms that use alloys with high percentages of the metal might be unable to meet the standard. This would not be apparent looking solely at aggregate industry data. OSHA should take reasonable steps to determine that those that did not meet the standard do not have important technological or economic characteristics that are different from those that did.

Under this approach, OSHA could conclude that a standard is feasible where a state already had such a standard if it first determines that (1) the standard is enforced; (2) employers in the state in fact meet the standard; and (3) which of the relevant industries and technologies are represented within that state.

However, in spite of these caveats, it would frequently take OSHA less time and fewer resources to demonstrate that a standard is technologically and economically feasible by showing that employers in the industry already meet the standard than by the full identification of control technologies, exposure levels achieved by those technologies, the costs of the technologies, and the economic impacts of these technologies that OSHA now undertakes.

As noted above, at one point in the *Lead I* decision, the court suggested OSHA develop a ''reasonable estimate of costs.'' However at another point in this decision the same court clarified:

> [T]he court probably cannot expect hard and precise estimates of costs. Nevertheless,

the agency must of course provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry . . . And OSHA can revise any gloomy forecast that estimated costs will imperil an industry by allowing for the industry's demonstrated ability to pass through costs to consumers. *Lead I,* 647 F.2d at 1266. *(Ex. #12)*

OSHA has made little use of the concept of a likely range of costs or of developing generic approaches to determining a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.

OSHA could significantly reduce its resource and time expenditures by providing ranges of costs, given that the upper end of the range provides ''a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.'' Such an approach would not only reduce OSHA's time and effort but also that of the interested public. Too often stakeholders devote significant time and effort questioning cost estimates when even the stakeholders' alternative cost estimate would have no effect on whether the costs would threaten the existence or competitive structure of an industry. The simple fact is that both OSHA and its stakeholders spend far too much time examining the accuracy of cost estimates even when the highest cost estimates considered would have little effect on the determination of economic feasibility.

OSHA could also make more effort to clarify historically the circumstances under which regulations of any kind have eliminated or altered the competitive structure of an industry. As noted above, OSHA has yet to find an instance in which OSHA regulations eliminated or altered the competitive structure of an industry. A more thorough exploration of past experiences with OSHA regulations might simplify OSHA analyses and make it more empirically based in a variety of situations.

OSHA believes that it may be able to meet the requirements of Executive Orders 12866 and 13563 and the Regulatory Flexibility Act without the kind of industry-by-industry detail that OSHA now provides in its economic analyses. The requirements of executive orders for analysis of costs and benefits do not include requirements that they be made available on an industry-by-industry basis, and OIRA encourages the reporting of ranges as opposed to precise but possibly inaccurate point estimates. OSHA believes that the requirements of the executive orders and for determining if a regulatory flexibility analysis or Small Business Regulatory Enforcement Fairness Act (SBREFA) Panel is needed can, in most cases, be met by focusing on those sectors and size classes where the most severe impacts are expected.

Question IV.C.1: Should OSHA consider greater use of process oriented regulations, such as regulations on abrasive blasting, welding, or degreasing, as an approach to health standards? Should such an approach be combined with a control banding approach?

Question IV.C.2: Should OSHA consider issuing substance-specific standards in segments as the analysis of a particular process or industry is completed rather than waiting until every process and industry using a substance has been thoroughly analyzed?

Question IV.C.3: To what extend and in what circumstances can OSHA argue that feasibility for a regulatory alternative can be established by the enforcement of a lower PEL (e. g., the 1989 PEL) by an individual state or states?

4. Approaches to Economic Feasibility Analysis for a Comprehensive PELs Update

Following the Eleventh Circuit's direction in the *Air Contaminants* case (956 F.2d at 980–82; Ex. #8) and in *Color Pigments Mfrs. Ass'n* v. *OSHA,* 16 F.3d 1157, 1161–64 (11th Cir. 1994; Ex. #13), OSHA has typically performed its economic feasibility analyses on an industry-by-industry basis using the lowest level industry codes for which industry data are available. While such an approach best insures that the effect of the standard on small industry segments will be considered, it is very resource intensive. If OSHA were required to use of this approach to address feasibility for a comprehensive PELs update, which would require addressing the feasibility of new PELs for hundreds of chemicals in hundreds of industry segments, it might require more resources than the agency would have available.

There are good reasons to think that the OSH Act does not require such a detailed level of economic analysis to support a feasibility finding. The purpose of the OSH Act is to assure all workers ''safe and healthful working conditions,'' and therefore it is unlikely that Congress intended for OSHA to meet such demanding analytical requirements if it meant that the agency could not issue a standard addressing well-recognized hazards. *See, e.g., Public Citizen Health Research Group* v. *Dep't of Labor,* 557 F.3d 165, 178–79 (3d Cir. 2009; Ex. #14) (''*Hexchrome*'') (rejecting interpretation that OSH Act required OSHA to research all workplace operations involving hexavalent chromium exposure to prove feasibility, which would ''severely hinder OSHA's ability to regulate exposure to common toxins''); *American Dental Ass'n* v. *Martin,* 984 F.2d 823, 827 (7th Cir. 1993; Ex. #53) (OSHA not required to regulate ''workplace by workplace''); *Assoc. Bldrs & Contrs. Inc.* v. *Brock,* 862 F.2d 63, 68 (3d Cir. 1988; Ex. #54) (''A requirement that the Secretary assess risk to workers and need for disclosure with respect to each substance in each industry would effectively cripple OSHA's performance of the duty imposed on it by 29 U.S.C. 655(b)(5); a duty to protect all employees, to the maximum extent feasible.'').

Indeed, the requirement that an OSHA standard not threaten ''massive dislocation'' or ''imperil the existence'' of an industry is an outgrowth of the idea that OSHA may adopt standards that may cause marginal firms to go out of business if they are only able to make a profit by endangering their employees. *See Industrial Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467, 478 (XX Cir. 1974; Ex. #55). And the notion that the determination must be made on an industry basis arises from cases in which OSHA attempted to do just that; the statute does not require feasibility to be evaluated in this way. *See Lead I,* 647 F.2d at 1301 (where OSHA attempted to determine the feasibility of the lead standard on an industry-by-industry basis, noting that the parties did not dispute that feasibility was to be determined in that manner); *Hexchrome,* 557 F.3d at 178 (''nothing in 29 U.S.C. 655(b)(5) requires OSHA to analyze employee groups by industry, nor does the term 'industry' even appear''). The approach articulated by the *Air Contaminants* court, which places an affirmative duty on OSHA to establish that proposed standards would not threaten even the smallest industry segments before adopting a standard, creates a heavy analytical burden that is not necessarily required by the statute.

As the *Lead I* court notes, in the case of a standard requiring an employer to adopt only those engineering and administrative controls that are feasible, what really is at stake in OSHA's feasibility determinations is whether OSHA has justified creating a presumption that the implementation of such controls are feasible. 647 F.2d at 1269–70. Thus, OSHA need not ''prove the standard certainly feasible for all firms at all times in all jobs.'' 647 F.2d at 1270. The court recognized that under

this approach, some employers might not be able to comply with a standard, but noted that the statute offers those employers several alternatives: requesting a variance, asserting a feasibility defense in an enforcement proceeding, or petitioning the agency to revise the standard. 647 F.2d at 1270.

As noted above, most of OSHA's current PELs are over 40 years old, and are based on science that is even older. It seems unlikely that a statute enacted to protect workers against chemical health hazards would preclude OSHA from updating hundreds of those PELs unless it can show that each is feasible in each of the smallest industry segments in which the chemical is used. The question, then, is what level of analysis would be sufficient to justify a presumption that the standard is feasible, shifting the burden to the employer as allowed by *Lead I*.

If OSHA moved forward with a global PELs update, the Agency might consider analyzing economic feasibility at a higher level than it has typically employed in substance specific health standards. In order to do so, OSHA would need to develop criteria as to what chemicals are suited to be part of a PELs rulemaking rather than subject to a substance-specific rulemaking. For example, if the rulemaking record showed that, for a specific chemical application group, generally available exposure controls had not been successful in achieving the proposed PEL, then this chemical or at least the application group would be transferred from updated PELs rulemaking to being a candidate for further study and possible inclusion in a substance-specific rulemaking. The goal under this approach would be to develop a reasonable basis for believing that the chemicals and application groups remaining in a PELs-update rulemaking are (1) likely to be economically feasible; and (2) subject to relatively simple and easily-costed controls that are likely to be relatively homogenous across industries.

As a result, rather than accumulating data at the lowest industry level available regarding exposures and controls needed for each chemical for which a new PEL would be adopted, OSHA could consider a more general approach. For example, OSHA might conduct an economic feasibility analysis at the industry level for which sufficient exposure data are currently available. It might use a control banding approach in order to determine the types of controls necessary to comply with a new PEL, and validate models to implement each type of control based on variables such as establishment size and process type. The results of this analysis would be used to build up costs at the industry level. It is possible that the results of such an analysis might be better characterized in ranges, and of sufficient precision to establish feasibility at a level as low as the method that OSHA typically uses. Under this approach, a determination made in this way would be presumptively sufficient to establish feasibility in the absence of contrary evidence provided by commenters. If such evidence were presented, OSHA would address it and incorporate it into its feasibility analysis supporting the final rule.

Question IV.C.4: Should OSHA consider providing ranges of costs for industries in situations where even the upper range of the costs would obviously not provide a threat to the existence of competitive structure of an industry?

Question IV.C.5: What peer-reviewed economics literature should OSHA consult when determining whether the competitive structure of an industry would be altered? Are there any instances where an OSHA standard did threaten the existence or competitive structure of an industry? What were they and what is the evidence that an OSHA standard was the origin of the difficulties?

Question IV.C.6: Should OSHA consider and encourage substitution and elimination of substances that cause significant risk in workplaces even if such substitution or elimination will eliminate or alter the competitive structure of the industry or industries that produce the hazardous substance?

Question IV.C.7: Are there other approaches OSHA could use that would provide for more timely and less resource-intensive economic feasibility analyses?

Question IV.C.8: In determining the level of industry detail at which OSHA should conduct an economic feasibility analysis for a comprehensive PELs update, what considerations should OSHA take into account? What level of detail do you think is sufficient to justify the presumption of feasibility for such a standard? Please explain.

Question IV.C.9: Are the methodologies suggested above appropriate to establish economic feasibility for a comprehensive PELs update? Why or why not? What other cost effective methods are available for OSHA to establish economic feasibility for such a rulemaking?

Question IV.C.10: What factors should OSHA consider in determining whether a chemical should be part of an overall PELs update or subject to substance-specific rulemaking? Should OSHA consider some application groups for a given chemical as subject to a PELs update rulemaking if some other application groups present feasibility issues that make them inadvisable candidates for a PELs rulemaking?

V. Recent Developments and Potential Alternative Approaches

Wide access to information on the Internet and the development of a global economy has shifted occupational safety and health from a domestic to a global concern. Countries often struggle with similar experiences and challenges related to exposure to hazardous chemicals, and sharing information and experiences across borders is a common practice. Global data sharing allows for the widespread and rapid dissemination of available chemical information to employers, employees, managers, chemical suppliers and importers, risk managers, or anyone with access to the Internet. The development of hazard assessment tools that take advantage of readily available hazard information make it possible for employers to implement effective exposure control strategies without the need to rely solely on OELs.

Some of these resources for data and tools that OSHA may use more systematically in the future for hazardous chemical identification and/or assessment are addressed in Section V.

A. Sources of Information About Hazardous Chemicals

In order to design and implement appropriate protective measures to control chemical exposures in the workplace, employers need reliable information about the identities and hazards associated with those chemicals. OSHA is considering ways in which recently developed data sources could be used by the Agency and employers to more effectively manage chemical hazards in the workplace. Developments in the use of structure—activity data for grouping chemicals having similar properties, the Environmental Protection Agency's High Production Volume (HPV) Chemicals, OSHA's Hazard Communication standard and the Globally Harmonized Hazard Communication Standard, health hazard banding, the European Union's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), are discussed here. OSHA is interested in stakeholders' comments on how the Agency may make use of any of these data sources or other alternative data or information sources not discussed here

to better manage workplace chemical exposures.

1. EPA's High Production Volume Chemicals

One potential source of relevant and timely information on chemicals that OSHA may make better use of in the future is the data on High Production Volume chemicals that are being collected by the EPA and the Organization for Economic Cooperation and Development (OECD). The OECD program lists approximately 5,000 chemicals on its list, and OSHA has determined that 290, or 62 percent of the 470 substances with PELs are included on the OECD list.

Under the HPV program, EPA has identified over 2,000 chemicals that are produced in quantities of one million pounds a year or more in the United States. It would appear that these chemicals are thus economically significant in the US, and there are likely to be a large number of workers exposed to them. Through the HPV Challenge program, EPA encouraged industry to make health and environmental effects data on these HPV chemicals publicly available. To date, data on the properties of approximately 900 HPV chemicals has been made available through the Agency's High Production Volume Information System (HPVIS) (U.S. EPA, 2012a; *Ex. #56*). For each HPV chemical, the database includes information on up to 50 endpoints on physical/chemical properties, environmental fate and pathways, ecotoxicity, and mammalian health effects. EPA has also used this information to generate publicly available chemical hazard characterizations, which provide a concise assessment of the raw technical data on HPV chemicals and evaluate the quality and completeness of the data received from industry (U.S. EPA, 2013d; *Ex. #63*).

Data on HPV chemicals submitted through the OECD's program are available through its Global Portal to Information on Chemical Substances, eChemPortal (OECD, 2013; *Ex. #58*). In addition to searching data collected through the EPA HPV and OECD HPV programs, eChemPortal allows for simultaneous searching of 26 databases for existing publicly available data on the properties of chemicals, including: physical/chemical properties, environmental fate and behavior, ecotoxicity, and toxicity.

Question V.A.1. How might publicly available information on the properties and toxicity of HPV chemicals be utilized by employers to identify chemical hazards and protect workers from these hazards? OSHA is also interested to hear from commenters who may currently make use of these data in their worker protection programs.

2. EPA's CompTox and ToxCast

EPA has also launched an effort to prioritize the tens of thousands chemicals that are currently in use for testing and exposure control. Through its computational toxicology (CompTox) research, the U.S. Environmental Protection Agency (EPA) is working to figure out how to change the current approach used to evaluate the safety of chemicals. CompTox research integrates advances in biology, biotechnology, chemistry, and computer science to identify important biological processes that may be disrupted by the chemicals and trace those biological disruptions to a related dose and human exposure. The combined information helps prioritize chemicals based on potential human health risks. Using CompTox, thousands of chemicals can be evaluated for potential risk at a small cost in a very short amount of time. A major part of EPA's CompTox research is the Toxicity Forecaster (ToxCast™). ToxCast is a multiyear effort launched in 2007 that uses automated chemical screening technologies, called ''highthroughput screening assays,'' to expose living cells or isolated proteins to chemicals. The cells or proteins then are screened for changes in biological activity that may suggest potential toxic effects.

These innovative methods have the potential to limit the number of required animal-based laboratory toxicity tests while, quickly and efficiently screening large numbers of chemicals. The first phase of ToxCast, called ''proof of concept'', was completed in 2009, and it evaluated more than 300 well studied chemicals (primarily pesticides) in more than 500 high-throughput screening assays. Because most of these chemicals already have undergone extensive animal-based toxicity testing, this enables EPA researchers to compare the results of the high-throughput assays with those of the traditional animal tests. (EPA, 2014a; *Ex. #59*)

Completed in 2013, the second phase of ToxCast evaluated over 2,000 chemicals from a broad range of sources, including industrial and consumer products, food additives, and potentially ''green'' chemicals that could be safer alternatives to existing chemicals. These chemicals were evaluated in more than 700 high-throughput assays covering a range of high-level cell responses and approximately 300 signaling pathways. ToxCast research is ongoing to determine which assays, under what conditions, may lead to toxicological responses. The results of this research then can be used to suggest the context in which decision makers can use the data. The EPA's Endocrine Disruptor Screening Program already has begun the scientific review process necessary to begin using ToxCast data to prioritize the thousands of chemicals that need to be tested for potential endocrine-related activity. Other potential uses include prioritizing chemicals that need testing under the Toxic Substances Control Act and informing the Safe Drinking Water Act's contaminant candidate lists. (EPA, 2014b; *Ex. #60*) EPA contributes the results of ToxCast to a Federal agency collaboration called Toxicity Testing in the 21st Century (Tox21). Tox21 pools those results with chemical research, data and screening tools from the National Toxicology Program at the National Institute of Environmental Health Science, the National Institutes of Health's National Center for Advancing Translational Sciences and the Food and Drug Administration. (EPA, 2014b; *Ex. #60*)

Thus far, Tox21 has compiled highthroughput screening data on nearly 10,000 chemicals. All ToxCast chemical data are publicly available for anyone to access and use through user-friendly Web applications called interactive Chemical Safety for Sustainability (iCSS) Dashboards at *http://actor.epa.gov/actor/faces/*.

OSHA could use this publicly available information on chemical properties and toxicity as a part of the Agency's risk assessments that support the revision and development of permissible exposure limits. Tox21 could also be used by the Agency for screening chemicals and prioritizing for risk management.

Question V.A.2. How might the information on the properties and toxicity of chemicals generated by CompTox, ToxCast, and/or Tox21 be utilized by employers to identify chemical hazards and protect workers from these hazards? OSHA is also interested to hear from commenters who may currently make use of these data in their worker protection programs.

3. Production and Use Data Under EPA's Chemical Data Reporting Rule

Under the EPA's Chemical Data Reporting (CDR) Rule, issued in 2011, EPA collects screening-level, exposure-related information on certain chemicals included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory and makes that information publicly available to the extent possible. The CDR rule amended the TSCA Inventory Update Reporting (IUR) rule

and significantly increased the type and amount of information covered entities are required to report. The 2012 submissions included data on more chemicals and with more in-depth information on manufacturing (including import), industrial processing and use, and consumer and commercial use than data collected under the IUR in 2006 (U.S. EPA, 2013a; *Ex. #1*).

The expanded reporting on chemical production and use information under the CDR could help OSHA better understand how workers are exposed to chemicals and the industries and occupations where exposures to chemicals might occur.

4.Structure-Activity Data for Chemical Grouping

Although toxicity testing for chemicals has increased greatly since the passage of the Toxic Substances Control Act (15 U.S.C. 2601–2629; *Ex. #62*) in the United States, and with similar legislation elsewhere, toxicity data is only publicly available for a fraction of industrial chemicals. Since the enactment of TSCA and creation of the TSCA Interagency Testing Committee (U.S. EPA, 2013c; *Ex. #57*), the ITC has recommended testing for hundreds of chemicals, and chemical producers have conducted more than 900 tests for these chemicals. However, potentially thousands of industrial chemicals have not been tested.

With the rapidly expanding development of new chemical substances and mixtures, the need for toxicity information to inform chemical safety management and public health decisions in a timely manner has exceeded the capacity of the government programs to provide those data. As a result, programs such as the Organization for Economic Cooperation and Development's (OECD) Screening Information Data Set (SIDS) and the U.S. EPA High Production Volume (HPV) Challenge programs were designed to encourage the voluntary development of data. However, even with the creation of these non-statutory programs, potentially thousands of non-HPV industrial chemicals go untested. Therefore, chemical prioritization for screening and testing requires the development and validation of standard methods to predict the human and environmental effects and potential fate of chemicals. Where screening and testing data are sparse, the use of predictive models called structural activity relations (SARs) or quantitative structural activity relationships (QSARs) can extend the use of limited toxicity and safety data for some untested chemicals (Russom *et al.,* 2003; *Ex. #64*). QSARs are mathematical models that are used to predict measures of toxicity from physical characteristics of the structure of chemicals, known as molecular descriptors.

Other U.S. and international agencies have explored the use of chemical groupings to regulate chemicals in order to fulfill their regulatory and statutory authorities. Under the TSCA Work Plan, the EPA announced in 2013 that it would begin to assess 20 flame retardant chemicals and three non-flame retardant chemicals. EPA utilized a structure-based approach, grouping eight other flame retardants with similar characteristics together with the chemicals targeted for full assessment in three groupings. EPA will use the information from these assessments to better understand the other chemicals in the group, which currently lack sufficient data for a full risk assessment.

EPA uses chemical groupings to fill data gaps in its New Chemical Program. EPA's New Chemical Program, also under TSCA, requires anyone who plans to manufacture or import a new chemical substance into commerce to provide EPA with notice before initiating the activity. This is called a pre-manufacture notification (PMN). EPA received approximately 1,500 new chemical notices each year and has reviewed more than 45,000 from 1979 through 2005 (GAO, 2007; *Ex. #65*). Because TSCA does not require testing before submission of a PMN, SARs and QSARs are often used to predict the environmental fate and ecologic effects. In addition, the EPA makes predictions concerning chemical identity, physical/chemical properties, environmental transport and partitioning, environmental fate, environmental toxicity, engineering releases to the environment, and environmental concentrations. The agency uses a variety of methods to make these predictions that include SARs, nearest-analogue analysis, chemical class analogy, mechanisms of toxicity, and chemical industry survey data and the collective professional judgment of expert scientific staff, in the absence of empirical data. The agency uses these methods to fill data gaps in an assessment and to validate submitted data in notifications. Predictions are also made by the U.S. EPA Office of Pollution Prevention and Toxics (OPPT) under TSCA (Zeeman., 1995; *Ex. #66*). The OPPT has routinely used QSARs to predict ecologic hazards, fate, and risks of new industrial chemicals, as well as to identify new chemical testing needs, for more than two decades. OPPT SAR/QSARs for physical/chemical properties used for new chemical assessments are publically available (U.S. EPA, 2012b; *Ex. #67*).

In Europe, internationally agreed-upon principles for the validation of (Q)SARs were adopted by OECD Member Countries and the Commission in 2004. In 2007, the Inter-organization Programme for the Sound Management of Chemicals, a cooperative agreement among United Nations Environmental Program (UNEP); International Labor Organization (ILO); Food and Agriculture Organization of the United Nations (FAO); World Health Organization (WHO); United Nations Industrial Development Organization (UNIDO), United Nations Institute for Training and Research (UNITAR) and Organization for Economic Co-operation and Development (OECD) published ''Guidance on Grouping of Chemicals'' as part of an ongoing monograph series on testing chemicals. REACH registrants may rely on (Q)SAR data instead of experimental data, provided the registrants can provide adequate and reliable documentation of the applied method and document the validity of the model. Validation focuses on the relevance and reliability of a model (ECHA, 2008; *Ex. #68).*

The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) recommended, in their general data requirements for regulatory submission, that QSAR data may be used as well as animal data. A chemical category approach based on the metal ion has been extensively used for the classification and labeling of metal compounds in the EU. Other category entries are based on certain anions of concern such as oxalates and thiocyanates. For these EU classifications the category approach has often been applied to certain endpoints of particular concern for the compounds under consideration, but has not necessarily been applied to all endpoints of each individual compound in the category of substances.

The Danish EPA has made extensive use of QSARs and has developed a QSAR database that contains predicted data on more than 166,000 substances (OSPAR Commission, 2000; *Ex. #69*). A recent publication from the Danish EPA reports the use of QSARs for identification of potential persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances from among the HPV and medium-production volume chemicals in the EU.

OSHA is considering using a combination of chemical group approaches to evaluate multiple chemicals with similar attributes

utilizing limited data that can be extrapolated across categories. The Agency invites comment on how such grouping approaches have been used to evaluate risks to worker populations.

Question V.A.3: Are QSAR, read-across, and trend analysis useful and acceptable methods for developing hazard information utilizing multiple data sets for a specific group of chemicals?

Question V.A.4: Are there other acceptable methods that can be used to develop hazard information for multiple chemicals within a group?

Question V.A.5: What are the advantages and disadvantages of each method?

5. REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals in the European Union (EU)

Safe chemical management is a universal concern. The European Union, recognizing the need for a more integrated approach to chemical management, adopted REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) to address chemicals throughout their life cycle. Although REACH applies to European Union Member States, chemical manufacturers in other countries exporting to European countries also have to comply with the REACH requirements to sell their products in Europe.

The REACH Regulation (EC) No 1907/2006 became effective on June 1, 2007, and relies on the generation and disclosure of data by manufacturers and importers of chemicals in order to protect human health and the environment from chemical hazards. The regulation also established the European Chemicals Agency (ECHA) to coordinate implementation (EC 1907/2006, 2006; *Ex. #70*).

REACH establishes processes for the Registration, Evaluation, Authorization, and Restriction of Chemicals. REACH requires manufacturers and importers to register their chemicals and establish procedures for collecting and assessing information on the properties, hazards, potential risks and uses of their chemicals. The registration process, which began in 2010, is being phased-in based on the tonnage and hazard classification of the substances. For existing chemicals, it is set to be completed in June 2018.

For each chemical manufactured or imported in quantities of 1 ton or more per year, companies must register the substance by providing a technical dossier to ECHA. The technical dossier includes information on: Substance identity; physicochemical properties; mammalian toxicity; ecotoxicity; environmental fate; manufacture and use; and risk management measures (ECHA, 2012b; *Ex. #71*). Non-confidential information from the technical dossiers is published on the ECHA Web site (ECHA, 2012c; *Ex. #72*).

Companies manufacturing or importing a chemical in quantities of 10 or more tons per year must also conduct a chemical safety assessment. This assessment includes the evaluation of: (1) Human health hazards; (2) physicochemical hazards; (3) environmental hazards; and (4) persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) potential (ECHA, 2012b; *Ex. #71*). If a substance is determined to be hazardous or a PBT/vPvB, registrants must then conduct an exposure assessment, including the development of exposure scenario(s) (ES) and exposure estimation, and a risk characterization that includes development of a health effects benchmark, such as the Derived No Effect Level (DNEL).

An exposure scenario, the main output of the exposure assessment process, documents a set of operational conditions and risk management measures for a specific use of a substance. A number of exposure estimation models have been developed in the EU to help the regulated community create these exposure scenarios. Exposure scenarios must also be included in the Safety Data Sheets (SDS) in order to communicate this information down the supply chain. When an extended SDS with exposure scenarios is received by a chemical user, the exposure scenarios must be reviewed to determine if they are applicable to the use situation in that facility. If the exposure scenarios are applicable, the user has 12 months to implement them. If they are not, the user has several options to choose from to determine appropriate controls. These options include: (1) User informing supplier of their use, and user convincing supplier to recognize it as an ''identified use'' on suppliers safety assessment; (2) user implementing the suppliers conditions of use described in the exposure scenario of the original/current safety assessment; (3) user substituting the substance for another substance that is covered in a pre-existing safety assessment; (4) user finding another supplier who does provide an exposure scenario that covers the use of the substance; or (5) prepare a downstream user chemical safety report. (ECHA, 2012c; *Ex. #72*).

After completing the exposure assessment, registrants conduct a risk characterization process to determine if the operational conditions cause exposures that require risk management measures to ensure risks of the substance are controlled. Risk characterization consists of the comparison of exposure values derived from each exposure scenario with their respective DNEL or an analogous health benchmark such as Derived Minimal Effect Level (DMEL) or Predicted No Effect Concentration (PNEC)), established by the registrant. Where no health benchmark is available, a qualitative risk characterization is required (ECHA, 2009; *Ex. #73*).

Manufacturers and importers are required to document the information developed during the chemical safety assessment in a chemical safety report, which is submitted to ECHA. The report then forms the basis for other REACH processes, including substance evaluation, authorization, and restriction.

ECHA and the EU Member States then evaluate the information submitted during the registration process to examine the testing proposals, check the quality of the registration dossiers, and evaluate whether a substance constitutes a risk to human health or the environment. Following the evaluation process, registrants may be required to comply with additional actions to address concerns (*i.e.,* submit further information, proceed on restriction or authorization procedures under REACH, take actions under other legislation, etc.). (ECHA, 2012d; *Ex. #74*).

As the implementation of REACH continues, large amounts of information will be generated by manufacturers, importers, and downstream users throughout the registration, authorization, and restriction processes. Some of this information is publicly available on ECHA Web sites, and includes toxicological information, general exposure control recommendations, and assessments of the availability of alternatives. The generation and availability of this extensive data on chemicals can assist OSHA, as well as U.S. employers and workers, to further enhance chemical safety and health management by assisting in the assessment of hazards, development of exposure control recommendations, and selection of substitutes to help drive the transition to safer chemicals in the workplace.

As of July, 2013, the REACH database of registered substances is comprised of more than 9900 substances. The database provides extensive information to the public from dossiers prepared by chemical manufacturers, importers, and downstream users. OSHA is interested

in determining whether some information developed and submitted under REACH may be helpful to OSHA in its own regulatory initiatives. Information submitted under REACH's requirements to assess chemical risks in workplaces may be useful in developing task-based exposure control plans, or of use in OSHA's feasibility analyses. OSHA is participating in high-level discussions with the EU about the feasibility of sharing these data.

Question V.A.6: OSHA is interested in the experiences of companies that have had to prepare chemical dossiers and submit registration information to the European Chemicals Agency (ECHA) ECHA. In particular, how might the approaches be used to support occupational exposure assessments and development of use-specific risk management in the United States?

Question V.A.7: To what extent is information developed under REACH used by U.S. businesses to promote product stewardship and ensure safe use of substances and mixtures by product users?

Question V.A.8: Should OSHA pursue efforts to obtain data from ECHA that companies are required to provide under REACH?

B. Non-OEL Approaches to Chemical Management

OSHA's PELs and its corresponding hierarchy of controls have been a major focus in the fields of occupational health and industrial hygiene for many years. Undoubtedly, occupational exposure limits (OELs), which help reduce workers' risk of adverse health by establishing precise targets for employers to follow, will always be an essential part of controlling chemical exposures in workplaces. However, regardless of whether a more effective process for updating OSHA's PELs can be established, the rapid development of new chemical substances and mixtures that will continue to leave workers exposed to thousands of unregulated substances make it impractical to solely rely on OELs. Moreover, for many of the chemicals and mixtures that have been developed since the PELs were initially promulgated, insufficient hazard information exists to serve as a basis for developing OELs. While OELs generally focus on a single chemical, workers are typically exposed to mixtures or multiple substances in the workplace. Mixed exposures may also result in synergistic or antagonistic effects that are rarely considered in developing OELs.

Workplace risk assessments, and corresponding risk management plans, should be based on an evaluation of all hazards present—OELs established for a few chemicals among the many in the workplace environment have diminished impact in these situations. Unlike OELs, which are only useful in protecting workers if regular measurement and assessment of compliance is completed, alternative risk management approaches focus more on determining what types of controls are required to reduce exposures without necessarily referring to quantitative assessments of exposure to evaluate success.

An important aspect of risk assessment and risk management is consideration of safer alternatives, which can often result in a path forward that is less hazardous, technically feasible, and economically viable.

1. Informed Substitution to Safer Chemicals and Processes

While establishing exposure limits for hazardous chemicals helps to reduce workers' risk of adverse health effects, the process is costly, time consuming, and does not drive the development or adoption of safer alternatives that could best protect workers. OSHA recognizes that ultimately, an approach to chemical management that incentivizes and spurs the transition to safer chemicals, products, and processes in a thoughtful, systematic way will most effectively ensure safe and healthful conditions for workers.

Informed substitution, the considered transition from hazardous chemicals to safer substances or non-chemical alternatives, provides a way of moving toward a more preventative chemical management framework.

a. Substitution in Practice

Whenever a hazardous chemical is regulated, there is always the potential for the chemical to be replaced with a substitute chemical or redesigned product or process that poses new and potentially greater hazards to workers, consumers, or the environment or results in risk-shifting from one group to another. Regrettably, this potential has been realized in a number of cases. For example:

- The regulation of methylene chloride by EPA, FDA, and OSHA spurred the shift to 1-bromopropane, an unregulated neurotoxicant and possible carcinogen, in a variety of applications, such as refrigeration, metal cleaning, and vapor and immersion degreasing applications, as well as in adhesive resins (Kriebel et al., 2011; *Ex. #75*).
- Air quality regulations in California created a market in the vehicle repair industry for solvent products formulated with n-hexane, a neurotoxicant causing symptoms of peripheral neuropathy, and hexane-acetone blends, which amplify the neurotoxic effects of n-hexane, thus resulting in risk-shifting from the environment to workers (Wilson *et al.,* 2007; *Ex. #76*).

While regulatory processes lacking a robust assessment of alternatives can result in substitution that is equally detrimental to human health or the environment, regulatory efforts that require planning processes and provide guidance and technical assistance on preferred alternatives can minimize risk trade-offs and protect workers, consumers, and the environment. For example, in Massachusetts, facilities using specific toxic chemicals in certain quantities are required to undertake a toxics use reduction planning process. Agencies provide various resources to encourage and facilitate the voluntary adoption of alternatives. In the case of trichloroethylene, the Massachusetts Office of Technical Assistance and the Toxics Use Reduction Institute provided technical assistance, educational workshops, a database of safer alternatives, and performance evaluations of alternatives (Toxics Use Reduction Institute, 2011a; *Ex. #78;* Toxics Use Reduction Institute, 2011b; *Ex. #79;* Toxics Use Reduction Institute, 2011c; *Ex. #80*). Through these efforts, Massachusetts companies reduced the use of trichloroethylene by 77 percent since 1990, moving to a number of safer alternatives in the process (Toxics Use Reduction Institute, 2011d; *Ex. #81*).

These cases demonstrate that the transition to safer chemicals, materials, products, and processes will be best facilitated not through restrictions or bans of chemicals, but rather through the integration of informed substitution and guidance on preferred alternatives into regulatory efforts.

b. Benefits of a Preference for Primary Prevention Strategies

The reduction or elimination of a hazard at the source, as traditionally embraced by health and safety professionals, is not only the most reliable and effective control approach, but also provides a number of benefits for workers and businesses.

Preferring primary prevention strategies (*i.e.* elimination and substitution) can result in the ''total elimination of exposure to hazardous chemicals, less reliance on worker compliance or equipment maintenance for success, elimination of the potential for accidental or non-routine overexposures, prevention of dermal exposures, and process and environmental improvements not

related to worker health'' (Roelofs et al., 2003; *Ex. #82*).

Additionally, making process improvements designed to reduce or eliminate workers' exposures to hazardous chemicals often results in significant business improvements or savings. A 2008 study by the American Industrial Hygiene Association (AIHA) demonstrated the relationship between the application of the hierarchy of controls and financial benefits. The study found that the greatest cost savings and other benefits tended to be associated with hazard elimination and the elimination of personal protective equipment (PPE) usage. It also highlighted the ability of material substitution to result in very large payoffs due to the creation of efficiencies throughout the business process (American Industrial Hygiene Association, 2008; *Ex. #83*). For example:

- A foundry making automatic diesel engine blocks enhanced and aggressively enforced a purchasing specification program to eliminate supplied scrap metal contaminated with lead. By eliminating lead from its supply chain, the company not only achieved high levels of employee protection, but also enhanced the quality of its products and realized nearly $20 million in savings for the facility.
- An aircraft manufacturing company, struggling to comply with the OSHA PEL for hexavalent chromium, transitioned from chromate-based primers to non-chromate based primers, resulting not only in the elimination of worker exposure to chromate dusts from rework sanding, but also in quality improvements of its products, increased customer satisfaction, productivity gains, avoidance of costly changes to their exhaust ventilation system, and a savings of $504,694 over the 5-year duration of the project.

c. Informed Substitution

In order to truly protect workers from chemical hazards, it is important that OSHA not only develop health standards for hazardous chemicals, but also understand alternatives to regulated chemicals and support a path forward that is less hazardous, technically feasible, and economically viable. Informed substitution provides a framework for meeting this goal.

As previously described, informed substitution is the considered transition from a potentially hazardous chemical, material, product, or process to safer chemical or non-chemical alternatives. The goals of informed substitution are to minimize the likelihood of unintended consequences, which can result from a precautionary switch away from a hazardous chemical without fully understanding the profile of potential alternatives, and to enable a course of action based on the best information that is available or can be estimated. Informed substitution approaches focus on identifying alternatives and evaluating their health, safety, and environmental hazards, potential trade-offs, and technical and economic feasibility.

Substitution is not limited to substitution of one chemical with another. It can also occur at the production process or product level. At the product level, substitution may involve a design change that takes advantage of the characteristics of new or different materials. A chemical process design change may eliminate several production steps thereby avoiding or reducing the use of high hazard chemicals. In some cases, a particular chemistry or the function it serves may be determined to be unnecessary.

As implementation of chemical substitution and product and process changes can be quite complicated, a variety of processes, tools, and methods are critical to achieving informed substitution.

Substitution planning, similar to facility planning for pollution prevention and source reduction, establishes practical steps for evaluating substitution as a workplace risk reduction measure. This type of planning process supports informed substitution by encouraging chemical users to: Systematically identify hazardous chemicals; set goals and priorities for the elimination or reduction of hazardous chemicals; evaluate alternatives; identify preferred alternatives; and promote the adoption of identified alternatives.

Alternatives assessment is a process of identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals or technologies of concern on the basis of their hazards, performance, and economic viability. A variety of alternatives assessment processes have been developed to date (Lavoie et al., 2010; *Ex. #84;* Toxics Use Reduction Institute, 2006; *Ex. #85;* Rossi et al., 2006; *Ex. #86;* Raphael et al., 2011; *Ex. #87*). Various tools and methods have been developed to evaluate hazard, performance, and cost when assessing alternatives. For example, comparative chemicals hazard assessments compare potential alternatives based on a variety of hazard endpoints in order to select a safer alternative. Some examples of comparative chemicals hazard assessment tools include the GreenScreen (Clean Production Action, 2012; *Ex. #88*) and Design for the Environment (DfE) Safer Product Labeling Program (U.S. EPA, 2011a; *Ex. #89*). Other existing methods for chemical comparison include the Column Model (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung, 2011; *Ex. #90*) and QuickScan (Netherlands Ministry of Infrastructure and the Environment, 2002; *Ex. #91*). Tools and methods for evaluating performance and cost attributes, while less well developed, are also critical for the selection of a preferred alternative.

d. Substitution at OSHA

Substitution is not new for OSHA. Historically, OSHA attempted to encourage substitution by setting a ''no occupational exposure level'' for certain potential carcinogens where suitable substitutes that are less hazardous to humans existed for particular uses (45 FR 5257–58; *Ex. #92*). Although this requirement was never fully implemented, the final rule detailed a process for the Agency to analyze the feasibility of substitutes, which required the consideration of: (1) the safety of the substitute, including the comparative acute and chronic toxicity of the carcinogenic chemical and the substitute, and other relevant factors, such as environmental factors; (2) the technical feasibility of the substitute, including its relative effectiveness; and (3) the economic cost of substitution (45 FR 5258; *Ex. #92,* 29 CFR 1990.111(k); *Ex. #93,* see also 1990.132(b)(6); *Ex. #94,* 1990.146(k); *Ex. #95*).

OSHA health standards also identify substitution as a preferred exposure control. For example, in the 1989 Air Contaminants Standard, the Agency refers to substitution, when properly applied, as ''a very effective control technique'' and ''the quickest and most effective means of reducing exposure'' (54 FR 2727, 2789; *Ex. #7*). In addition, the Agency's respiratory protection standard mandates the use of accepted engineering control measures, including the substitution of less toxic materials, as far as feasible, before using respirators to control occupational diseases caused by breathing contaminated air (29 CFR 1910.134(a); *Ex. #96*). Despite this, when complying with PELs and other health standards in practice, employers are required to select and implement administrative or engineering controls before using personal protective equipment, but are not specifically required or encouraged to consider elimination or substitution

before other engineering or administrative controls. (See 29 CFR 1910.1000(e); *Ex. #97*). Thus, substitution may be often overlooked in favor of other approaches, such as ventilation and isolation, when employers are controlling exposures to hazardous chemicals.

OSHA also considers substitution during the development of PELs. While OSHA does not solely rely on substitution to make its required feasibility findings (62 FR 1494, 1576; *Ex. #98;* 71 FR 10099, 10260; *Ex. #99*), the Agency, as part of PEL rulemaking efforts, develops and evaluates information about substitution in its technological and economic feasibility analysis, highlighting options available for eliminating or reducing the regulated chemical's use in various industries and applications. For example, the feasibility analysis for methylene chloride describes numerous substitute chemicals and processes, including a detailed table of substitute paint removal methods for 16 applications, and evaluates the relative risks for seven of the more common substitutes for methylene chloride (OSHA, 1996; *Ex. #100*). However, the analysis of substitutes has varied widely from regulation to regulation. For example, the feasibility analysis for hexavalent chromium identifies specific substitute chemicals and processes in many industries, but does not discuss the health or safety hazards of the substitutes (OSHA, 2006a; *Ex. #101*), while the feasibility analysis for formaldehyde includes only a mention of the availability of one identified substitute for a few industry sectors (OSHA, 1987; *Ex. #102*) and the feasibility analysis for ethylene oxide does not contain any discussion of substitutes (OSHA, 1984; *Ex. #103*).

OSHA has also included information on substitutes in a variety of non-regulatory documents. New information about available substitutes and substitution trends is included in lookback reviews of existing standards conducted by the Agency (*e.g.,* lookback review of the ethylene oxide standard, lookback review of the methylene chloride standard) (OSHA, 2005; *Ex. #104;* OSHA, 2010; *Ex. #105*). In some cases, OSHA has also developed information on substitution, even where a PEL has not been established. For example, the OSHA guidance document on the best practices for the safe use of glutaraldehyde in health care includes information about drop-in replacements and alternative processes available to reduce or eliminate the use of the chemical (OSHA, 2006b; *Ex. #106*).

In October 2013, OSHA launched an effort to encourage employers, workers, and unions to proactively reduce the use of hazardous chemicals in the workplace and achieve chemical use that is safer for workers and better for business. As part of this effort, the Agency developed a web toolkit that guides employers and workers in any industry through a seven-step process for transitioning to safer chemicals (OSHA, 2013a; *Ex. #107*). Each step contains information, resources, methods, and tools that will help users eliminate hazardous chemicals or make informed substitution decisions in the workplace by finding a safer chemical, material, product, or process.

e. Possible Opportunities for Integrating Informed Substitution Approaches Into OSHA Activities

There are a variety of existing regulatory and non-regulatory models for incorporating informed substitution into chemical management activities. The following are some examples of entities that have developed and utilized informed substitution approaches as part of regulatory efforts; guidance and policy development; education, training, and technical assistance activities; and data development and research efforts.

i. Models for Regulatory Approaches

Some regulations and voluntary standards require risk reduction through the implementation of a hierarchy of controls that clearly delineates elimination and substitution as preferred options to be considered and implemented, where feasible, before other controls. For example, the ANSI/AIHA Z10–2005 standard for Occupational Health and Safety Management Systems, a voluntary national consensus standard, requires organizations to implement and maintain a process for achieving feasible risk reduction based upon the following preferred order of controls: A. Elimination; B. Substitution of less hazardous materials, processes, operations, or equipment; C. Engineering controls; D. Warnings; E. Administrative Controls; and F. Personal protective equipment (ANSI/AIHA Z10–2005, 2005; *Ex. #108*). European Union Directives 98/24/EC and 2004/37/EC require employers to eliminate risks by substitution before implementing other types of protection and prevention measures (98/24/EC, 1998; *Ex. #109,* 2004/37/EC, 2004; *Ex. #110*).

Some existing laws require firms to undertake planning processes for the reduction of identified hazardous chemicals. For example, the Massachusetts Toxics Use Reduction Act requires entities that use listed hazardous chemicals in certain quantities to undertake a planning process for reducing the use of those chemicals (Massachusetts Department of Environmental Protection, n.d.; *Ex. #77*).

Existing regulations in the European Union place a duty on employers to replace the use of certain hazardous chemicals with safer substitutes, if technically possible. For example, Directive 2004/37/EC requires the substitution of carcinogens and mutagens with less harmful substances where technically feasible (2004/37/EC, 2004) and Directive 98/24/EC requires employers to ensure that risks from hazardous chemical agents are eliminated or reduced to a minimum, preferably by substitution (98/24/EC, 1998; *Ex. #109*).

Other regulations require the use of acceptable substitutes where the uses of certain hazardous chemicals are phased-out. This type of approach is currently implemented by U.S. EPA in the context of phasing-out ozone depleting substances. The Clean Air Act requires that these substances be replaced by others that reduce risks to human health and the environment. Under the Significant New Alternatives Policy (SNAP) program, EPA identifies and publishes lists of acceptable and unacceptable substitutes for ozone-depleting substances (Safe Alternatives Policy, 2011; *Ex. #111*).

Some chemical management frameworks require the assessment of substitutes before making decisions to limit or restrict the use of a hazardous chemical. For example, the European Union REACH Regulation (Registration, Evaluation, Authorization and Restriction of Chemicals) requires that an analysis of alternatives, the risks involved in using any alternative, and the technical and economic feasibility of substitution be conducted during applications of authorization for substances of very high concern (EC 1907/2006, 2006; *Ex. #70*).

Other efforts to spur the transition to safer chemicals, products, and processes are based on the development of criteria-based standards for functions or processes that rely on hazardous chemicals. For example, the EPA DfE Safer Product Labeling Program is a nonregulatory program that recognizes safe products using established criteria-based standards. In order to receive DfE recognition, all chemicals in a formulated product must meet Master Criteria (*i.e.,* toxicological thresholds for attributes of concern, including: acute

mammalian toxicity; carcinogenicity; genetic toxicity; neurotoxicity; repeated dose toxicity; reproductive and developmental toxicity; respiratory sensitization; skin sensitization; environmental toxicity and fate; and eutrophication), as well as relevant functional-class criteria (*i.e.,* additional toxicological thresholds for attributes of concern for surfactants, solvents, direct-release products, fragrances, and chelating and sequestering agents), established by the EPA (U.S. EPA, 2011a; *Ex. #89*).

While there are a number of ways in which OSHA could consider integrating substitution and alternatives assessment into its regulatory efforts, the Agency, in order to promulgate any such standard, would need to make the significant risk, technological feasibility, and economic feasibility findings required under the OSH Act. However, even without regulation, it is important to consider voluntary models for incorporating informed substitution into chemical management activities.

ii. Models for Guidance Development

Some entities have developed guidance to promote the transition to safer alternatives. The European Union, in order to support legislative substitution mandates, developed guidance on the process of substitution, including setting goals, identifying priority chemicals, evaluating substitutes, selecting safer alternatives, and implementing chemical, material, and process changes. The guidance establishes and describes a seven step substitution framework, providing workplaces with a systematic process for evaluating chemical risk and identifying chemicals that could or should be substituted (European Commission, 2012; *Ex. #113*). The steps include: Assessing the current level of risk; deciding on risk reduction needs; assessing the margins of change; looking for alternatives; checking the consequences of a change; deciding on change; and deciding on how and when to implement change.

Similarly, the German Federal Institute for Occupational Safety and Health (BAuA) established guidance to support the employer's duty, as mandated in the German Hazardous Substances Ordinance, to evaluate substitutes to hazardous substances and implement substitution where less hazardous alternatives are identified (German Federal Institute for Occupational Safety and Health, 2011; *Ex. #114*). The guidance, TRGS 600, includes a framework for identifying and evaluating substitutes and establishes criteria for assessing and comparing the health risks, physicochemical risks, and technical suitability of identified alternatives (German Federal Institute for Occupational Safety and Health, 2008; *Ex. #115*).

The German Environment Agency has also developed guidance on sustainable chemicals. The guide assists manufacturers, formulators, and end users of chemicals in the selection of sustainable chemicals by providing criteria to distinguish between sustainable and non-sustainable substances (German Environment Agency, 2011; *Ex. #116*).

OSHA considered developing guidance on safer substitutes to accompany individual chemical exposure limit standards in its 2010 regulatory review of methylene chloride. Due to the increased use of other hazardous substitutes after methylene chloride was regulated in 1998, the Agency considered establishing guidance recommending that firms check the toxicity of alternatives on the EPA and NIOSH Web sites before using a substitute (OSHA, 2010; *Ex. #105*).

iii. Models for Education, Training, and Technical Assistance

Other entities have developed outreach, training, and technical assistance efforts for substitution planning and the assessment of substitutes for regulated chemicals. The Massachusetts Toxics Use Reduction Act, which established a number of structures to assist businesses, provides a good example of such efforts. The Massachusetts Office of Technical Assistance and Technology (OTA) provides compliance assistance and on-site technical support that helps facilities use less toxic processes and boost economic performance. The Massachusetts Toxics Use Reduction Institute provides training, conducts research, and performs alternatives assessments in order to educate businesses on the existence of safer alternatives and promote the on-the-ground adoption of these alternatives. Toxics Use Reduction Planners (TURPs), certified by the Massachusetts Department of Environmental Protection (MA DEP), prepare, write and certify the required toxics use reduction plans and are continually educated about best practices in toxics use reduction. Taken together, these services provide a robust resource for regulated businesses on the transition to safer alternatives (Massachusetts Department of Environmental Protection, n.d.; *Ex. #77*).

iv. Models for Data Development

Several efforts, at both the federal and international levels, attempt to support the transition to safer alternatives through research and data development. For example, EPA, in collaboration with the non-governmental organization GreenBlue and industry stakeholders, jointly developed a database of cleaning product ingredient chemicals (surfactants, solvents, fragrances, and chelating agents) that meet identified environmental and human health criteria (GreenBlue, 2012; *Ex. #117*). In Spain, the Institute of Work, Environment, and Health (ISTAS) has developed a database that is a repository of information on substitute chemicals. The database can be searched for chemical substances, uses/products, processes, or sectors to display information on substitutes and hazards associated with those substitutes (ISTAS, 2012; *Ex. #118*). In addition, the European Union SUBSPORT project has begun to create a Substitution Support Portal, a state-of-the-art resource on safer alternatives to the use of hazardous chemicals. The resource is intended to provide not only information on alternative substances and technologies, but also tools and guidance for substance evaluation and substitution management (SUBSPORT, 2012; *Ex. #119*).

Other efforts focus on the completion of alternatives assessments for priority chemicals and uses. Currently, EPA's Design for the Environment Program, as well as the Massachusetts Toxics Use Reduction Institute, has conducted alternatives assessments for priority chemicals and functional uses, making this information publicly available in the process (U.S. EPA, 2012c; *Ex. #120;* Toxics Use Reduction Institute, 2006; *Ex. #85*).

In addition, some research efforts attempt to fill data gaps with regards to the toxicological properties of existing chemicals. While some efforts to conduct toxicity testing for chemicals is taking place at the federal level (U.S. EPA, 2011b; *Ex. #121,* U.S. EPA, 2012d; *Ex. #122*), there have not been systematic efforts to conduct targeted toxicology studies for specific substitutes of interest.

Question V.B.1: To what extent do you currently consider elimination and substitution for controlling exposures to chemical hazards?

Question V.B.2: What approaches would most effectively encourage businesses to consider substitution and adopt safer substitutes?

Question V.B.3: What options would be least burdensome to industry,

especially small businesses? What options would be most burdensome?

Question V.B.4: What information and support do businesses need to identify and transition to safer alternatives? What are the most effective means to provide this information and support?

Question V.B.5: How could OSHA leverage existing data resources to provide necessary substitution information to businesses?

v. Effectively Implementing Informed Substitution Approaches

The goals of informed substitution cannot be achieved without the development and application of tools and methods for identifying, comparing, and selecting alternatives. Existing tools and methods range in complexity, from quick screening tools to detailed comparative hazard assessment methodologies to robust frameworks for evaluating alternatives based on hazard, performance, and economic feasibility. Illustrative examples, which represent the range of tools available, are described below.

Some assessment tools provide methods for rapid evaluation of chemical hazards based on readily available information. These types of tools are critical for small and medium-sized businesses, which often lack resources and expertise to evaluate and compare chemical hazards. In the state of Washington, the Department of Ecology (DOE) has developed the Quick Chemical Assessment Tool (QCAT) to allow businesses to identify chemicals that are not viable alternatives to a chemical of concern by assigning an appropriate grade for the chemical based on nine high priority hazard endpoints (Washington Department of Ecology, 2012; *Ex. #123*). Similarly, the Institute for Occupational Safety and Health of the German Federation of Institutions for Statutory Accident Insurance and Prevention (IFA) developed the Column Model as a tool for businesses to evaluate chemicals based on six hazard categories using information obtained from chemical safety data sheets (IFA, 2011; *Ex. #90*).

Other existing tools provide more detailed methodologies for conducting a comparative hazard assessment, which require greater expertise, data, and resources to complete. The GreenScreen, created by Clean Production Action, provides a methodology for evaluating and comparing the toxicity based on nineteen human and environmental hazard endpoints, assigning a level of concern of high, moderate, or low for each endpoint based on various established criteria (Clean Production Action, 2012; *Ex. #88*).

A number of robust frameworks have also been developed to assess the feasibility of adopting alternatives for hazardous chemicals based on environmental, performance, economic, human health, and safety criteria. The Massachusetts Toxics Use Reduction Institute developed and implemented a methodology for assessing alternatives to hazardous chemicals based on performance, technical, financial, environmental, and human health parameters (TURI, 2006; *Ex. #85*). Similarly, the U.S. EPA DfE program has also developed and implemented an alternatives assessment framework to characterize alternatives based on the assessment of chemical hazards as well as the evaluation of availability, functionality, economic, and life cycle considerations (Lavoie et al., 2010; *Ex. #84,* U.S. EPA, 2012c; *Ex. #120*).

Although some tools and methods exist, as discussed above, further research and development in this area is critical for the effective implementation of informed substitution.

Question V.B.6: What tools or methods could be used by OSHA and/or employers to conduct comparative hazard assessments? What criteria should be considered when comparing chemical hazards?

Question V.B.7: What tools or methods could be used by OSHA and/or employers to evaluate and compare the performance and cost attributes of alternatives? What criteria should be considered when evaluating performance and cost?

2. Hazard Communication and the Globally Harmonized System (GHS)

OSHA promulgated its Hazard Communication Standard (HCS) (29 CFR 1910.1200; *Ex. #124*) in 1983 to require employers to obtain and provide information to their employees on the hazards associated with the chemicals used in their workplaces. After thirty years of implementation, the HCS has resulted in extensive information being disseminated in American workplaces through labels on containers, safety data sheets (SDSs), and worker training programs.

On March 26, 2012, OSHA published major modifications to the HCS. (77 FR 17574–17896; *Ex. #125).* These modifications are being phased in over several years, and will be completely implemented in June 2016. Referred to as HazCom 2012, the revised rule incorporates a new approach to assessing the hazards of chemicals, as well as conveying information about them to employees. The revised rule is based on the United Nations' Globally Harmonized System for the Classification and Labeling of Chemicals (GHS), which established an international, harmonized approach to hazard communication.

The original HCS was a performance-oriented rule that prescribed broad rules for hazard communication but allowed chemical manufacturers and importers to determine how the information was conveyed. In contrast, HazCom 2012 is specification-oriented. Thus, while the HCS requires chemical manufacturers and importers to determine the hazards of chemicals, and prepare labels and safety data sheets (SDSs), HazCom 2012 goes further by specifying a detailed scheme for hazard classification and prescribing harmonized hazard information on labels. In addition, SDSs must follow a set order of information, and the information to be provided in each section is also specified.

Hazard classification means that a chemical's hazards are not only identified, they are characterized in terms of severity of the effect or weight of evidence for the effect. Thus, the assessment of the hazard involves identifying the ''hazard class'' into which a chemical falls (*e.g.,* target organ toxicity), as well as the ''hazard category''—a further breakdown of the hazardous effect generally based on either numerical cut-offs, or an assessment of the weight of the evidence. For target organ toxicity, for example, chemicals for which there is human evidence of an effect are likely to be classified under Category 1, the most hazardous category, thus indicating the highest classification for the effect. If the only data available are animal studies, the chemical may fall in Category 2—still potentially hazardous to humans, but lower in terms of the weight of evidence for the effect. Table-I illustrates how such a chemical hazard classification may be assigned by hazard class and hazard category

Table-I

Health Hazards

Hazard Class	Hazard Category			
Acute Toxicity	1	2	3	4
Skin Corrosion/Irritation	1A	1B	1C	2
Serious Eye Damage/ Eye Irritation	1	2A	2B	
Respiratory or Skin Sensitization	1			
Germ Cell Mutagenicity	1A	1B	2	
Carcinogenicity	1A	1B	2	
Reproductive Toxicity	1A	1B	2	Lactation
STOT – Single Exposure	1	2	3	
STOT – Repeated Exposure	1	2		
Aspiration	1			
Simple Asphyxiants	Single Category			

OSHA, 1910.1200, Appendix A

The process of classifying chemicals under HazCom 2012 means that all chemicals will be fully characterized as to their hazards, as well as degree of hazardous effect, using a standardized process with objective criteria. Thus, OSHA could use this system to select certain hazard classes and categories to set priorities. For example, the Agency could decide to identify substances that are characterized as Class 1 Carcinogens or as Reproductive Toxicants as its priorities. Then chemicals that fall into those hazard categories could be further investigated to determine other relevant factors, such as numbers of employees exposed, use of the chemical, risk assessment, etc. The HazCom 2012 information could lead to a more structured and consistent priority system than previously attempted approaches. (*Ex. #126)* OSHA could also investigate whether the hazard categories lend themselves to establishing regulatory provisions for hazard classes and categories rather than for individual substances. The availability of specific hazard categorization for chemicals could allow this to be done on a grouping basis—either in regulation, or in guidance.

Once a chemical is placed into a hazard class and hazard category, HazCom 2012 (and the GHS) specifies the harmonized information that must appear on the label. Referred to as ''label elements,'' these include a pictogram, signal word, hazard statement(s), and precautionary statement(s). In addition, the label must have a product identifier and supplier contact information. The use of standardized label elements will help to ensure consistency and comprehensibility of the information, which will make HazCom 2012 more effective in terms of conveying information to employees and employers. The approach taken in the GHS strengthens the protections of the OSHA HCS in several ways, and introduces the possibility of the Agency using the information generated under HazCom 2012 to help frame a more comprehensive approach to ensuring occupational chemical safety and health.

3. Health Hazard Banding

''Health hazard banding'' can be defined as a qualitative framework to develop occupational hazard assessments given uncertainties caused by limitations in the human health or toxicology data for a chemical or other agent. Health hazard banding presumes it is possible to group chemicals or other agents into categories of similar toxicity or hazard characteristics.

Health hazard banding assigns chemicals with similar toxicities into hazard groups (or bands. The occupational health professional can use this classification or hazard band, along with information on worker exposures to the substance, to do exposure risk assessment. Hazard banding, along with exposure information, is a useful risk assessment tool, particularly in situations where toxicity data are sparse. Hazard banding can also aid in the prioritization and hazard ranking of chemicals in the workplace. NIOSH is working with OSHA and a variety of stakeholder groups (federal agencies, industry, labor organizations, and professional associations) to develop guidance on establishing the technical criteria, decision logic, and minimum dataset for the hazard band process.

4. Occupational Exposure Banding

NIOSH has proposed an approach, occupational exposure banding, which would sort chemicals into five bands (A

through E), with each band representing a different hazard level. Chemicals with the lowest toxicity would be grouped in Band A, while the moist toxic chemicals would be grouped in Band E. The proposed process includes a three-tiered evaluation system based on the availability of toxicological data to define a range of concentrations for controlling chemical exposures. A Tier 1 evaluation relies on hazard codes and categories from GHS, and intended for chemicals for which little information exists. Therefore, a chemical in Band D or E in the Tier 1 process is a bad actor and should be targeted for elimination and or substitution. Tier 2 and 3 require professional expertise. Once NIOSH completes their validation work of the three tiers, they plan to develop tools to facilitate evaluating hazard data and assigning chemicals to hazard bands as well as educational materials for health and safety professionals, managers, and workers. (*Exs. #127 & #128)*

5. Control Banding

Control banding is a well-established approach of using the hazard statements from a label and/or safety data sheet (SDS) to lead an employer to recommended control measures. This approach has been used successfully in a number of countries, particularly in Europe where such as system of hazard classification has been in use for some time. HazCom 2012 opens up the possibility that control banding can be further developed and refined in the U.S., either as guidance or regulatory provisions. It is a particularly useful way to provide information for small businesses to effectively control chemicals without necessarily going through the process of exposure monitoring and other technical approaches to ensuring compliance. It also will give employers better information to conduct risk assessments of their own workplaces, and thus select better control measures.

Health hazard banding can be used in conjunction with control banding to use the information available on the hazard to guide the assessment and management of workplace risks. In fact, health hazard banding is the first step in the control banding process. Control banding determines a control measure (for example dilution ventilation, engineering controls, containment, etc.) based on a range or ''band'' of hazards (such as skin/eye irritant, very toxic, carcinogenic, etc.), and exposures (small, medium, or large exposure). This approach is based on the fact that there are a limited number of control approaches, and that many chemical exposure problems have been met and solved before. Control banding uses the solutions that experts have developed previously to control occupational chemical exposures, and suggests them for other tasks with similar exposure situations. It focuses resources on exposure controls, and describes how strictly a risk needs to be managed.

Control banding is a more comprehensive qualitative risk characterization and management strategy that goes further in assigning prescribed control methods to address chemical hazards. It is designed to allow employers to evaluate the need for exposure control in an operation and to identify the appropriate control strategy given the severity of the hazard present and magnitude of exposure. The strength of control banding is that it is based on information readily available to employers on safety data sheets (SDSs), without the need for exposure measurements or access to occupational health expertise (except in certain circumstances). Control banding involves not only the grouping of workplace substances into hazard bands (based on combinations of hazard and exposure information) but also links the bands to a suite of control measures, such as general dilution ventilation, local exhaust ventilation, containment, and use of personal protective equipment (PPE).

Under control banding, one must consider the chemical's hazardous properties, physical properties, and exposure potential in order to determine the level of exposure control desired. The criteria used for categorizing chemicals include hazard information such as flammability, reactivity, and the nature of known health effects. These characteristics are associated with defined hazard phrases (*e.g.,* ''Causes severe skin burns and eye damage'' or ''Causes liver damage,'' or ''Reproductive hazard''). These standardized phrases have been familiar in the EU as ''R-phrases'' and are found on SDSs.

Different hazard bands exist along a continuum ranging from less hazardous chemicals to more hazardous chemicals. Once the appropriate hazard group has been determined from the hazard statements (*e.g.,* ''Hazard Group B''), exposure potential is evaluated based on the quantity in use, volatility (for liquids), or particulate nature (for solids). After evaluating these properties and categorizing the chemical into hazard and exposure bands, the chemicals are matched, based on their band categorization, to the appropriate control strategy, with more stringent controls applied for substances that are placed in high-toxicity bands.

The Control of Substances Hazardous to Health (COSHH) guidance issued by the Safety Executive (HSE) of the United Kingdom is one model of control banding (Health and Safety Executive, 2013; *Ex. #129*). Under the 2002 COSHH regulation, employers must conduct a risk assessment to decide how to prevent employees from being exposed to hazardous substances in the workplace. COSHH principles first require that exposure is prevented by employers, to the extent possible, by means of:

- Changing the way tasks are carried out so that exposures aren't necessary anymore;
- Modifying processes to cut out hazardous by-products or wastes; or
- Substituting a non-hazardous or less hazardous substance for a hazardous substance with new substances (or use the same substance in a different form) so that there is less risk to health.

If exposures to hazardous substances cannot be prevented entirely, then COSHH requires employers to adequately control them (Control of Substances Hazardous to Health Regulations, 2002; *Ex. #130*). Recognizing that many small employers may not have access to the required expertise, and also to reduce the need for a professional and to promote consistency in the assessment process, the HSE developed an approach to assessment and control of chemical hazards using control banding methodologies spelled out in the 2002 regulation. This control banding approach is described in detail in COSHH Essentials. Employers may use the guidance spelled out in the COSHH Essentials guide to determine the appropriate control approach for the chemical hazard in question. Each control approach covers a range of actions that work together to reduce exposure: (1) General Ventilation, (2) Engineering Controls, (3) Containment, and lastly, (4) Special—a scenario where employers should seek expert advice to select appropriate control measures.

The first step outlined under the COSHH Essentials guidance is to consult the safety data sheet for each chemical in use. Employers must record the date of assessment, the name of the chemical being assessed, the supplier of the chemical, and the task(s) for which the chemical is used.

Step two involves the determination of the health hazard. Employers ascertain the hazard by assessing the possible health effects from the hazard statements provided on the SDS, the amount in use, and the dustiness or volatility of the chemical in use.

Employers reference the hazard statements found on chemical safety data sheets against a table of COSHH hazard groups in order to categorize them into the appropriate hazard group (''A'' through ''E'', and possibly ''S''). Chemicals in Group A tend to be regarded as less harmful and may, for example, cause temporary irritation. Chemicals in Group E are the most hazardous and include known carcinogens. Group S encompasses substances that have special considerations for damage caused via contact with the eyes or skin.

Additionally, Step two requires employers to make some determinations about the quantity and physical state of chemicals in use. They must decide if the amount of chemical in use would be described as ''small'' (grams or milliliters), ''medium'' (kilograms or liters), or ''large'' (tons or cubic meters). When in doubt, COSHH Essentials principles encourage employers to err on the side of the larger quantity in making their determination. Additionally, the physical state of chemicals effect how likely they are to get into the air and this affects the control approach to be utilized. For solids, COSHH Essentials guides employers to make a determination of either ''Low'', ''Medium'', or ''High'' dustiness based upon visible criteria observed during the use of these chemicals. Employers may also use look-up tables provided in the COSHH Essentials guide to make a determination of whether liquids have ''low'', ''medium'', or ''high'' volatility based upon the chemical's boiling point and ambient or process operating temperatures.

In Step three of the COSHH Essentials guide, employers identify the appropriate control approach. Tables provided by the COSHH Essentials guide show the control approaches for hazard groups ''A'' through ''E'' according to quantity of chemical in use and its dustiness/volatility. Table-II illustrates how the control approaches are assigned. The control approaches referred to by number in the table are: 1) General Ventilation, 2) Engineering Control, 3) Containment, and 4) Special. (Health and Safety Executive, 2009; *Ex. #131*).

TABLE-II

Look-up table to select Control Approach according to Hazard Group, amount, and dustiness or volatility (reproduced from HSG193)[1]

Amount used	Low volatility or dustiness	Medium volatility	Medium dustiness	High volatility or dustiness
	Hazard Group A substances			
Small	1	1	1	1
Medium	1	1	1	2
Large	1	1	2	2
	Hazard Group B substances			
Small	1	1	1	1
Medium	1	2	2	2
Large	1	2	3	3
	Hazard Group C substances			
Small	1	2	1	2
Medium	2	3	3	3
Large	2	4	4	4
	Hazard Group D substances			
Small	2	3	2	3
Medium	3	4	4	4
Large	3	4	4	4
	Hazard Group E substances			
All amounts	4	4	4	4

Note: the values in the box give the Control Approach: Exposure Predictor Band

Source: (HSE, 2009)

Additionally, the COSHH Essentials guide provides detailed control guidance sheets for a range of common tasks. Consultation of these task-specific guidance sheets constitutes Step four under COSHH Essentials. Step five of COSHH Essentials involves the employer deciding on how best to implement control measures as prescribed. COSHH Essentials principles also stress the importance of employers reviewing their assessments regularly, especially if there is a significant change in workplace processes or environment. Employers are encouraged to incorporate exposure level monitoring, health surveillance, and relevant training.

A number of European Union nations (*e.g.,* United Kingdom, Germany, France, Netherlands, Norway, and Belgium) and Asian nations (Singapore and Korea) already utilize control banding methods comparable to COSHH Essential methods for management of a variety of chemical exposures in the workplace.

A number of studies have been conducted to assess the validity of a control banding model for control of exposure to chemicals. Jones and Nicas (2006; *Ex. #132*) reviewed the COSHH Essentials model for hazard-banding in vapor degreasing and bag-filling tasks. Their study showed that the model did not identify adequate controls in all scenarios with approximately eighteen percent of cases leaving workers potentially under-protected. However, in a similar study, Hashimoto *et al.* (2007; *Ex. #133*) showed that hazard-banding tended to overestimate the level of control and therefore was more protective. In 2011, Lee *et al.* (*Ex. #134)* found that for a paint manufacturing facility using mixtures of chemicals with different volatilities, exposure to the chemicals with higher volatility had a higher likelihood to exceed the predicted hazard-band. Lee also recommended further research for more precise task identification to better enable implementation of task-specific control measures.

NIOSH provides a thorough review and critical analysis of the concepts, protective nature, and potential barriers to implementation of control banding programs (NIOSH, 2009; *Ex. #135*). NIOSH concluded that control banding can be used effectively for performing workplace risk assessments and implementing control solutions for many, but not all occupational hazards. Additionally, NIOSH found that while in some situations in which control banding cannot provide the precision and accuracy necessary to protect worker health, and in some cases control banding will provide a higher level of control than is necessary.

COSHH Essentials and other control banding concepts developed in Europe were based initially on the European Union's pre-GHS classification and labeling system. Since the European Union has adopted the GHS in its classification and labeling rules, these risk phrases will no longer be available. Control banding approaches are now based on the hazard statements in the GHS. OSHA's adoption of the GHS to modify the HCS opens up the opportunity to use a control banding approach to chemical exposures in American workplaces based on the hazard classification system. This would be an alternative to focusing on PELs that could achieve the goal of risk management for many chemicals and operations in workplaces.

OSHA is interested in exploring how it might employ these non-OEL approaches in a regulatory framework to address hazardous substances where the available hazard information does not yet provide a sufficient basis for the Agency's traditional approach of using risk assessment to establish a PEL. OSHA believes that a hazard banding approach could allow the Agency to establish specification requirements for the control of chemical exposures more efficiently, offering additional flexibility to employers, while maintaining the safety and health of the workforce. Although health hazard banding and control banding show some promise as vehicles for providing guidance to occupational health professionals for controlling exposures to workers, their use in a regulatory scheme presents challenges. For example, the agency would need to consider how, if it were to require such approaches, the OSH Act's requirement that standards that reduce significant risk to the extent feasible might be satisfied.

OSHA is also interested in exploring the development of voluntary guidelines for incorporation of control banding into safety and health management programs in U.S. workplaces. These efforts might include the development and dissemination of compliance assistance materials (publications, safety and health topic Web pages, computer software and smartphone apps, e-Tools) as well as consultation services to assist small businesses.

Question V.B.8: How could OSHA use the information generated under HazCom 2012 to pursue means of managing and controlling chemical exposures in an approach other than substance-by-substance regulation?

Question V.B.9: How could such an approach satisfy legal requirements to reduce significant risk of material impairment and for technological and economic feasibility?

Question V.B.10.: Please describe your experience in using health hazard and/or control banding to address exposures to chemicals in the workplace.

Question V.B.11.: Are additional studies available that have examined the effectiveness of health hazard and control banding strategies in protecting workers?

Question V.B.12.: How can OSHA most effectively use the concepts of health hazard and control banding in developing health standards?

V.B.13.: How might OSHA use voluntary guidance approaches to assist businesses (particularly small businesses) with implementing the principles of hazard banding in their chemical safety plans? Could the GHS chemical classifications be the starting point for a useful voluntary hazard banding scheme? What types of information, tools, or other resources could OSHA provide that would be most effective to assist businesses, unions, and other safety and health stakeholders with operationalizing hazard banding principles in the workplace?

Question V.B.14.: Should OSHA consider greater use of specification standards or guidance as an approach to developing health standards? If so, for what kinds of operations are specification approaches best suited?

6. Task-based Exposure Assessment and Control Approaches

Job hazard analysis is a safety and health management tool in which certain jobs, tasks, processes or procedures are evaluated for potential hazards or risks, and controls are implemented to protect workers from injury and illness. Likewise, task-based assessment and control is a system that categorizes the task or job activity in terms of exposure potential and requirements for specific actions to control the exposure are implemented, regardless of occupational exposure limits. Tasks are isolated from the deconstruction of a larger process that is in turn part of an overall operation or project in an industrial setting. As industrial engineering explores the optimization of complex processes or systems through an evaluation of the integrated system of people, equipment, materials, and other components, the task-based system attempts to evaluate work activities to define uniform exposure scenarios and their variables and establish targeted control strategies.

Task-based exposure potential can be defined using readily available data including process operating procedures, task observation and analysis, job activity description, chemical inventory and toxicity information (hazard communication), historical exposure data, existing exposure databases, employee surveys, and current exposure data. Based on this exposure assessment, the task is matched with specific requirements for exposure control. Control specifications can draw on a broad inventory of exposure controls and administrative tools to reduce and prevent worker exposure to the identified hazardous substances.

OSHA is interested in exploring task-based control approaches as a technique for developing specification standards for the control of hazardous substances in the workplace as an alternative or supplement to PELs. Such an approach may offer the advantage of providing employers with specific guidance on how to protect workers from exposure and reduce or eliminate the need for conducting regular exposure assessments to evaluate the effectiveness of exposure control strategies. OSHA has developed specification-oriented health standards in the past, in particular, those for lead and asbestos in construction.

More recently, OSHA developed a control-specification-based approach for controlling exposures to crystalline silica dust in construction operations (OSHA, 2009; *Ex. #136,* OSHA, 2013b; *Ex. #137*). Construction operations are particularly amenable to specification standards due to the task-based nature of the work. The National Institute for Occupational Safety and Health (NIOSH), the Center to Protect Workers' Rights—a research arm of the Building and Construction Trades Department, AFL-CIO—has developed and used a ''Task-Based Exposure Assessment Model (T–BEAM)'' for construction. The characteristic elements of T–BEAM are: (1) an emphasis on the identification, implementation, and evaluation of engineering and work practice controls; and (2) use of experienced, specially trained construction workers (construction safety and health specialists) in the exposure assessment process. A task-based approach was used because tasks, or specialized skills, form the single greatest thread of continuity in the dynamic environment of construction (Susi et al., 2000; *Ex. #138*).

A new American National Standards Institute Standard (ANSI A10.49) based on GHS health hazard categories and utilizing a task-based approach is also being developed to address chemical hazards in construction (ASSE, 2012; *Ex. #139*). The standard requires employers to first identify tasks involving the use of chemicals and create a hazard communication inventory for these tasks. Then the employer must determine the hazard level and exposure level, and finally develop a control plan based on the hazard and exposure classifications. If the chemicals used in the task are low hazard and the task is low exposure, then the control plan requires following the SDS and label precautions. If, however, the task involves greater than minimal hazard or exposure, a more protective control plan must be developed.

However, developing specification standards governing exposure to health standards for general industry operations presents a different challenge. Given the diversity in the nature of industrial operations across a range of industry sectors that might be affected by a chemical standard, OSHA is concerned that it will be more difficult to develop specification standards for exposure controls that are specific enough to clearly delineate obligations of employers to protect employees, and yet are general enough to provide employers flexibility to implement controls that are suitable for their workplaces and that allow for future innovation in control technologies.

Question V.B.15: OSHA requests comment on whether and how task-based exposure control approaches might be effectively used as a regulatory strategy for health standards.

VI. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, directed the preparation of this notice. OSHA is issuing this notice under 29 U.S.C. 653, 655, 657; 33 U.S.C. 941; 40 U.S.C. 3704 *et seq.;* Secretary of Labor's Order 1–2012 (77 FR 3912, 1/25/2012); and 29 CFR Part 1911.

Signed at Washington, DC, on September 30, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Appendix A: History, Legal Background, and Significant Court Decisions

I. Background

Since the OSH Act was enacted in 1970, OSHA has made significant achievements toward improving the health and safety of America's workers. The OSH Act gave ''every working man and woman in the Nation'' for the first time, a legal right to ''safe and healthful working conditions.'' OSH Act § 2(a); 29 U.S.C. 651. (*Ex. #9*) Congress recognized that ''the problem of assuring safe and healthful workplaces for our men and women ranks in importance with any that engages the national attention today.'' S. Rep. 91–1282 at 2 (1970; *Ex. #17*). Indeed, when establishing the OSH Act, Congress was concerned about protecting workers from known hazards as well as from the numerous new hazards entering the workplace:

Occupational diseases which first commanded attention at the beginning of the industrial revolution are still undermining the health of workers. . . . Workers in dusty trades still contract various respiratory diseases. Other materials long in industrial use are only now being discovered to have toxic effects. In addition, technological advances and new processes in American industry have brought numerous new hazards to the workplace. S. Rep. 91–1282 at 2.

Many of the occupational diseases first discovered during the industrial revolution, and which later spurred Congress to create OSHA, still pose a significant harm to U.S. workers. While the number of hazardous chemicals to which workers are exposed has increased exponentially due to new formulations of chemical mixtures, OSHA has not been successful in establishing standards that adequately protect workers from hazardous chemical exposures, even from the older, more familiar chemicals.

OSHA's PELs are mandatory limits for air contaminants above which workers must not be exposed. OSHA PELs generally refer to differing amounts of time during which the worker can be exposed: (1) Time weighted averages (TWAs) which establish average limits for eight-hour exposures; (2) short-term limits (STELs) which establish limits for short term exposures; and (3) ceiling limits, which set never-to-be exceeded maximum exposure levels.

OSHA's PELs have existed nearly as long as the agency itself. Most of OSHA's current PELs were adopted by the agency in 1971. OSHA currently has PELs for approximately 470 hazardous substances, which are included in the Z-Tables in general industry at 29 CFR part 1910.1000 (*Ex. #4*) and in three maritime subsectors: Part 1915.1000 (Shipyard Employment; *Ex. #5*); part 1917 (Marine Terminals; *Ex. #140*); and part 1918 (Longshoring; *Ex. #141*). Z-Tables that apply in construction are found at part 1926.55 (*Ex. #6*). There are inconsistencies in the PELs that apply across industry sectors which resulted from the regulatory history of each divergent industry sector.

As discussed in further detail below, the Agency attempted to update the general industry PELs in 1989, but that revision was vacated by judicial decision in 1992. As such, the 1971 PELs remain the exposure limits with which most U.S. workplaces are required to comply. The Agency also promulgates ''comprehensive'' substance-specific standards (*e.g.,* lead, methylene chloride) which, in addition to PELs, require additional ancillary provisions such as housekeeping, exposure monitoring, and medical surveillance.

II. OSHA's Statutory Authority, Adoption of the PELs in 1971, and the 1989 Attempted Revision

A. The Purpose of the OSH Act and OSHA's Authority To Regulate Hazardous Chemicals

The OSH Act vests the Secretary of Labor with the power to ''promulgate, modify, or revoke'' mandatory occupational safety and health standards. OSH Act section 6(b), 29 U.S.C. 655(b). An ''occupational safety and health standard,'' as defined by section 3(8) of the OSH Act, is a ''standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' OSH Act section 3(8), 29 U.S.C. 652(8). (*Ex. #9)*

The OSH Act provides three separate approaches for promulgating standards. The first approach, in section 6(a) of the OSH Act, provided OSHA with an initial two-year window in which to adopt standards without hearing or public comment. Additionally, sections 6(b) and 6(c) provide methods currently available to the agency for promulgating health standards. Section 6(b) allows OSHA to create and update standards through notice and comment rulemaking, and section 6(c) provides OSHA with the authority to set emergency temporary standards. OSHA has not successfully adopted an emergency temporary standard for over thirty years, and it is not discussed further here.

B. The Adoption of the PELs Under Section 6(a)

Under section 6(a), OSHA was permitted to adopt ''any national consensus standard and any established Federal standard'' so long as the standard ''improved safety or health for specifically designated employees.'' 29 U.S.C. 655(a). The purpose of providing OSHA with this two-year window ''was to establish as rapidly as possible national occupational safety and health standards with which industry is familiar.'' S. Rep. 91–1282 at 6. When establishing this fast track to rulemaking, Congress emphasized the temporary nature of the approach, noting that these ''standards may not be as effective or up to date as is desirable, but they will be useful for immediately providing a nationwide minimum level of health and safety.'' S. Rep. 91–1282 at 6. (*Ex. #17*)

Establishing PELs was one of the first actions taken by OSHA. Most of the PELs contained in the Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000 (*Ex. #4*) for general industry, as well as those in construction and maritime were adopted during the initial two-year window under section 6(a). OSHA adopted approximately 400 occupational exposure limits for general industry that were based on the American Conference of Governmental Industrial Hygienist's (ACGIH) 1968 list of Threshold Value Limits (TLVs). In addition, about 25 additional exposure limits recommended by the American Standards Association (presently called the American National Standards Institute) (ANSI), were adopted as national consensus standards. 36 FR 10466 (*Ex. #142*). Currently the exposure limits that apply to construction were derived from the 1970 ACGIH TLVs and certain substance specific Sec. 6(b) standards.

The industry sector that is referred to today as ''Maritime'' has a long and somewhat confusing history. The Department of Labor has had some authority since 1958 for the maritime industry under the Longshore and Harbor Workers Compensation Act (33 U.S.C. 901 *et seq.*). Specifically authority was granted under Public Law 89–742 for the Secretary of Labor to issue regulations to protect the health and safety of longshoremen, marine terminal workers, ship repairers, shipbuilders, and ship breakers. Under Section 4(b)(2) of the OSH Act, 33 U.S.C. 941 (*Ex. #143*) became OSHA standards in 1971.

At that time, the Shipyard standards were in three parts of 29 CFR; part 1915 for ship repairing, part 1916 for shipbuilding and part 1917 for shipbreaking. In 1982 parts 1915, 1916 and 1917 were consolidated into a new part 1915, Shipyards. As a consequence of their history, the PELs applicable to the new part 1915, Shipyards, are complex. Depending upon the specific operation, either the 1970 TLVs or 1971 PELS (originally 1968 TLVs) apply. See §§ 1915.11, 1915.12, 1915.32 and 1915.33 (*Ex. #144*). Additionally, several of the OSHA single-substance standards apply.

Pursuant to the Longshoremen and Harbor Worker Compensation Acts of 1958 amendments, in 1960 OSHA issued regulations protecting longshore employees, along with marine terminal employees. These regulations were adopted as OSHA standards and later recodified. In 1983, OSHA issued a final standard specifically covering marine terminals (29 CFR part 1917) separately from longshoring. The Marine Terminal Standard basically requires that no employee be exposed to air contaminants over the limits set in the 1971 Z-Tables. See §§ 1917.2, 1917.22, 23, 25. (*Ex. #140*)

Longshoring operations continue to be regulated by 29 CFR Part 1918 *(Ex. #141).* OSHA has consistently interpreted that the air contaminant exposure limits set forth in 1910.1000 (*Ex. #4*) are applicable pursuant to 1910.5(c) to longshoring because no quantitative exposure limits are set forth for air contaminants, other than carbon monoxide.

As discussed above, the Agency was given authority to adopt standards to provide initial protections for workers from what the Congress deemed to be the most dangerous workplace threats. Congress felt that it was ''essential that such standards be constantly improved and replaced as new knowledge and techniques are developed.'' S. Rep. 91–1282 at 6. (*Ex. #17*) However, because OSHA has been unable to update the PELs, they remain frozen at the levels at which they were initially adopted. OSHA's PELs are largely based on acute health effects and do not take into consideration newer research regarding chronic effects occurring at lower occupational exposures. Thus, although there have been radical changes in our understanding of airborne contaminants, updates in technology, and changes to industry practices, OSHA's PELs are still based on research performed during the 1950s and 1960s. In contrast, the ACGIH annually reviews chemical substances and updates its list of TLVs®. Where OSHA currently has PELs for approximately 470 chemical hazards, the ACGIH recommends TLVs® for more than 700 chemical substances and physical agents, approximately 200 of which have been updated since 1971. (FACOSH, 2012; *Ex. #145*).

C. Section 6(b) Notice and Comment Rulemaking

Section 6(b) of the OSH Act provides OSHA with the authority to promulgate health standards. OSHA promulgates two main types of health standards: (i) PELs, and (ii) comprehensive standards, which, as the name implies, consist of provisions to protect workers in addition to PELs. Section 6(b)(5) imposes specific requirements governing the adoption of health standards:

[T]he Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

29 U.S.C. 655(6)(b)(5). (*Ex. #9*)

The courts have elaborated on the findings OSHA must make before adopting a 6(b)(5) standard. One such case, *Industrial Union Dept., AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980) (the *Benzene* case; *Ex. #10*), has had a major impact on OSHA rulemaking by establishing a threshold requirement that before the agency can promulgate a health standard it must show that a significant risk of material impairment exists, which can be eliminated or lessened by a change in practices. Additionally, the phrase ''to the extent feasible'' in section 6(b)(5) has been interpreted by the courts to require that OSHA show that a standard is both economically and technologically feasible. *American Textile* v. *Donovan,* 452 U.S. 490 (1981) (the *Cotton Dust* case; *Ex. #15*); *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1980) (the *Lead I* case; *Ex. #12*). These cases will be discussed in greater detail in Section III of this Appendix.

D. 1989 Air Contaminants Standard

In 1989, OSHA published the Air Contaminants final rule, which remains the Agency's most significant attempt at

updating the PELs. Unlike typical substance-specific rulemakings, where OSHA develops a comprehensive standard, the Air Contaminants final rule was only intended to update existing PELs and to add new PELs for substances not currently regulated. As such, the final rule did not include ancillary provisions (e.g. exposure monitoring, medical surveillance, requirements for personal protective equipment, or labeling) because OSHA determined that these provisions would delay and unnecessarily complicate the PELs update. Appendix B. to this Request for Information contains the table of PELs from the 1989 Air Contaminants Final Rule. The table includes both PELs originally adopted by OSHA in 1971 and the PELs established under the 1989 final rule.

In order to determine a starting point for updating the general industry PELs for chemicals on Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000 (*Ex. #4*), and for creating new PELs for some substances not listed in those tables, OSHA analyzed existing databases and lists of occupational exposure limits (OELs) to determine the scope of the rulemaking. After extensive review of all available sources of OELs, including the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Levels (RELs), the American Conference of Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs®), the American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Levels (WEELs), and limits from other countries, OSHA ultimately selected the ACGIH's 1987–88 TLVs to identify the basis for which substances and corresponding exposure values that would be included in the proposed rule. 53 FR 20977. The TLVs were selected as a reference point because of the number of substances they covered, the availability of written documentation on how the TLVs were selected, and the general acceptance of the TLVs by industrial hygienists, other occupational health professionals, and industry. (53 FR 20967; *Ex. #18,* 54 FR 2375; *Ex. #7*)

After determining the scope of hazardous chemicals to be included in the rulemaking, OSHA began the process of identifying the most appropriate new PELs to be proposed. OSHA considered both the ACGIH TLVs and the NIOSH RELs as a starting point. (53 FR 20966–67; *Ex. #18*) When the TLV and REL were similar, OSHA reviewed both the ACGIH documentation and the NIOSH recommendation. Where the TLV and REL ''differed significantly,'' OSHA reviewed the studies and reasoning upon which the NIOSH and ACGIH recommendations were based to determine which was more appropriate. OSHA presumed that a significant difference did not exist between the TLV and the REL for a chemical when:

(a) The TLV and REL values are the same;

(b) TLV and REL values differ by less than 10 percent;

(c) The TLV and REL Time Weighted Averages (TWA) are the same, but there are differences in the Short Term Exposure Limit (STEL) or Ceiling (C); or

(d) The TWA in one data base is the same, or one-half, the STEL/C in the other data base. 53 FR 20977.

In reviewing the evidence, OSHA first determined whether the studies and analyses were valid and of reasonable scientific quality. Second, it determined, based on the studies, if the published documentation of the REL or TLV would meet OSHA's legal requirements for setting a PEL. Thus, OSHA reviewed the evidence of significant risk at the existing PEL or, if there was no PEL, at exposures which might exist in the workplace in the absence of any limit. Third, OSHA reviewed the studies to determine if the new PEL would lead to substantial reduction in significant risk. 54 FR 2372.

OSHA's determination of where the new PEL should be set was based on its review and analysis of the information found in these sources. OSHA set the new PELs based on a review of the available evidence. 54 FR 2402. Safety factors were applied on a case-by-case basis. (54 FR 2365, 2399; *Ex. #7*). Based on the analysis discussed above, OSHA summarized the health evidence for each individual substance and determined when and at what level a new limit was necessary to substantially reduce a significant risk of material impairment of health or functional capacity among American workers. The following example illustrates the type of analysis that OSHA conducted for each substance:

OSHA had no former limit for potassium hydroxide. A ceiling limit of 2 mg/m(3) was proposed by the Agency based on the ACGIH recommendation, and NIOSH (Ex. 8–47, Table N1) concurred with this proposal. OSHA has concluded that this limit is necessary to afford workers protection from irritant effects and is establishing the 2-mg/m(3) ceiling limit for potassium hydroxide in the final rule.

[One commenter] (Ex. 3–830) commented that there was no basis for establishing an occupational limit for potassium hydroxide. OSHA disagrees and notes that the irritant effects of potassium hydroxide dusts, mists, and aerosols have been documented (ACGIH 1986/Ex. 1–3, p. 495; Karpov 1971/Ex. 1–1115). Although dose-response data are lacking for this substance, it is reasonable to expect potassium hydroxide to exhibit irritant properties similar to those of sodium hydroxide, a structurally related strong alkali. In its criteria document, NIOSH (1976k/Ex. 1–965) cites a personal communication (Lewis 1974), which reported that short-term exposures (2 to 15 minutes) to 2 mg/m(3) sodium hydroxide caused ''noticeable'' but not excessive upper respiratory tract irritation. Therefore, OSHA finds that the 2-mg/m(3) ceiling limit will provide workers with an environment that minimizes respiratory tract irritation, which the Agency considers to be material impairment of health. To reduce these risks, OSHA is establishing a ceiling limit of 2 mg/m(3) for potassium hydroxide. (54 FR 2332 et seq.*)*

OSHA proposed making 212 PELs more protective and setting new PELs for 164 substances not previously regulated by OSHA. Substances for which the PEL was already aligned with a newer TLV were not included.

In order to determine whether the Air Contaminants rule was feasible, OSHA prepared the regulatory impact analysis in two phases. The first phase of its feasibility analyses involved using secondary databases to collect information on the chemicals to be regulated and the industries in which they were used. These databases provided information on the toxicity and health effects of exposure to chemicals covered by the rulemaking, on engineering controls, and on emergency response procedures. (54 FR 2725; *Ex. #7*).

Two primary databases were used to collect information on the nature and extent of employee exposures to the substances covered by the rule. One database was the 1982 NIOSH National Occupational Exposure Survey (NOES), which collected information from 4,500 businesses on the number of workers exposed to hazardous substances. The second database was OSHA's Integrated Management Information System (IMIS) which contains air samples taken since 1979 by OSHA industrial hygienists during compliance inspections. OSHA also consulted industrial hygienists and engineers who provided information about the exposure controls in use, the number and size of plants that would be impacted by the rulemaking, and the estimated costs associated with meeting the new PELs. (54 FR 2373, 2725, 2736; *Ex. #7*).

As part of the second phase of its feasibility analyses, OSHA performed an industry survey and site visits. The survey was the largest survey ever conducted by OSHA and included responses from 5,700 firms in industries believed to use chemicals included in the scope of the Air Contaminants proposal. It was designed to focus on industry sectors that potentially had the highest compliance costs, identified through an analysis of existing exposure data at the four-digit SIC (Standards Industrial Classification) code level. 54 FR 2843. The survey gathered data on chemicals, processes, exposures and controls currently in use, which ''permitted OSHA to refine the Phase I preliminary estimates of technical and economic feasibility. Site visits to 90 firms were conducted to verify the data collected on chemicals, processes, controls, and employee exposures.'' 54 FR 2725; see also 54 FR 2736–39, 2768, 2843–69.

OSHA analyzed the data collected in phases I and II to determine whether the updated PELs were both technologically and economically feasible for each industry sector covered. 54 FR 2374.

For technological feasibility, OSHA evaluated engineering controls and work practices available within industry sectors to reduce employee exposures to the new PELs. In general, it found three types of controls might be employed to reduce exposures: Engineering controls, work practice and administrative controls, and personal protective equipment. Engineering controls included local exhaust ventilation, general ventilation, isolation of the worker and enclosure of the source of the emission, and product substitution. Work practice controls included housekeeping, material handling procedures, leak detection, training, and personal hygiene. Personal protective equipment included respirators, and where the chemicals involved presented skin

hazards, protective gloves and clothing. 54 FR 2789–90, 2840.

OSHA found that many processes required to reduce exposure were ''relatively standardized throughout industry and are used [to control exposures] for a variety of substances.'' 54 FR 2373–74. It ''examined typical work processes found in a cross section of industries'' and had industry experts identify the major processes that had the potential for hazardous exposures above the new PELs, requiring new controls. For each affected industry group, OSHA reviewed the data it had collected to ''identify examples of successful application of controls to these processes.'' 54 FR 2790. Based on its review OSHA found that ''engineering controls and improved work practices [were] available to reduce exposure levels in almost all circumstances.'' 54 FR 2727. In some cases, it found respirators or other protective equipment was necessary. 54 FR 2727, 2813–15, 2840. For each relevant industry sector (which was at the 2, 3, or 4 digit SIC code level, depending on the processes involved). As the court explained in Air Contaminants, 965 F.2d at 981 (*Ex. #8):*

The SIC codes classify by type of activity for purposes of promoting uniformity and comparability in the presentation of data. As the codes go from two and three digits to four digits, the groupings become progressively more specific. For example, SIC Code 28 represents ''Chemicals and Allied Products,'' SIC Code 281 represents ''Industrial Inorganic Chemicals,'' and SIC Code 2812 includes only ''Alkalies and Chlorine.''

OSHA prepared a list of the processes identified and the engineering controls and personal protective equipment (PPE) required to reach the new PELs. 54 FR 2814–39. In almost all cases, the OSHA list showed that the new PELs could be reached through a combination of ventilation and enclosure controls. 54 FR 2816–39. OSHA received and addressed numerous comments on the controls it proposed for use in various industries. 54 FR 2790–2813. OSHA found that ''in the overwhelming majority of situations where air contaminants [were] encountered by workers, compliance [could] be achieved by applying known engineering control methods, and work practice improvements.'' 54 FR 2789.

To assess economic feasibility, OSHA ''made estimates of the costs to reduce exposure based on the scale of operations, type of process, and degree of exposure reduction needed'' based primarily on the results of the survey. 54 FR 2373, 2841–51. For each survey respondent, OSHA identified the processes employed at the plant and made a determination about whether workers would be exposed to a chemical in excess of a new PEL. 54 FR 2843–47. For those processes where the new PEL would be exceeded, OSHA estimated the cost of controls necessary to meet the PEL. 54 FR 2947–51. Process control costs were then summed by establishment and costs ''for the survey establishment were then weighted (by SIC and size) to represent compliance costs for the universe of affected plants.'' 54 FR 2851. OSHA received and addressed many comments on its cost approach and assumptions. (54 FR 2854–62; *Ex. #7).*

Based on the survey, OSHA determined that 74 percent of establishments with hazardous chemicals had no exposures in excess of the new PELs and would incur no costs, 22 percent would incur costs to implement additional engineering controls, and 4 percent would be required to provide personal protective equipment only for maintenance workers. 54 FR 2851. OSHA estimated the total compliance cost to be $788 million per year annualized over ten years at a ten percent discount rate. 54 FR 2851. OSHA assessed the economic impact of the standard on industry profits on the two-digit SIC level. Assuming industry would not be able to pass the additional costs on to customers, the average change in profits was less than one percent, with the largest change in SIC 30 (Rubber and Plastics) of 2.3 percent. 54 FR 2885, 2887. Alternatively, assuming that industry could pass on all costs associated with the rule to its customers, OSHA determined that for no industry sector would prices increase on average more than half of a percent. 54 FR 2886, 2887. In neither case was the economic impact significant, OSHA found, and the new standard was therefore considered by the Agency to be economically feasible. (54 FR 2733, 2887; *Ex. #7)*

The Air Contaminants final rule was published on January 19, 1989. In the final rule, OSHA summarized the health evidence for each individual substance, discussed over 2,000 studies, reviewed and addressed all major comments submitted to the record, and provided a rationale for each new PEL chosen. The final rule differed from the proposal in a number of ways as OSHA changed many of its preliminary assessments presented in the proposal based on comments submitted to the record.

Ultimately, the final rule adopted more protective PELs for 212 previously regulated substances, set new PELs for 164 previously unregulated substances, and left unchanged an additional 52 substances, for which lower PELs were initially proposed. OSHA estimated over 21 million employees were potentially exposed to hazardous substances in the workplace and over 4.5 million employees were currently exposed to levels above the old PELs or in the absence of a PEL. OSHA projected the final rule would result in potential reduction of over 55,000 lost workdays due to illnesses per year and annual compliance with this final rule would prevent an average of 683 fatalities annually from exposures to hazardous substances. 54 FR 2725.

The update to the Air Contaminants standard generally received wide support from both industry and labor. However, there was dissatisfaction on the part of some industry representatives and union leaders, who brought petitions for review challenging the standard. For example, some industry petitioners argued that OSHA's use of generic findings, the inclusion of so many substances in one rulemaking, and the allegedly insufficient time provided for comment by interested parties created a record inadequate to support the new set of PELs. In contrast, the unions challenged the generic approach used by OSHA to promulgate the standard and argued that several PELs were not protective enough. The unions also asserted that OSHA's failure to include any ancillary provisions, such as exposure monitoring and medical surveillance, prevented employers from ensuring the exposure limits were not exceeded and resulted in less-protective PELs.

Fifteen of the twenty-five lawsuits were settled; of the remaining suits, nine were from industry groups challenging seven specific exposure limits, and one was from the unions challenging 16 substances. Pursuant to 28 U.S.C. 2112(a), all petitions for review were consolidated for disposition and transferred to the Eleventh Circuit Court of Appeals. *AFL–CIO* v. *OSHA,* 965, F.2d 962, 981–82 (11th Cir. 1992) (*Air Contaminants*). Although only 23 of the new PELs were challenged, the court ultimately decided to vacate the entire rulemaking, finding that ''OSHA [had] not sufficiently explained or supported its threshold determination that exposure to these substances at previous levels posed a significant risk of these material health impairments or that the new standard eliminates or reduces that risk to the extent feasible.'' *Air Contaminants,* 965 F.2d at 986–987; *Ex. #8.*

After publishing the Air Contaminants Final Rule for general industry, OSHA proposed amending the PELs for the maritime and construction industry sectors and establishing PELs to cover the agriculture industry sector. OSHA published a Notice of Proposed Rulemaking (NPRM) on June 12, 1992, which included more protective exposure limits for approximately 210 substances currently regulated in the construction and maritime industries and added new exposure limits for approximately 160 chemicals to protect these workers. (57 FR 26002; *Ex. #146*). The notice also proposed approximately 220 PELs to cover the agriculture industry. OSHA extended the comment period indefinitely while it considered possible responses to the *Air Contaminants* court decision. Once it became clear that an appeal would not be pursued, the Agency halted work on the project.

III. Significant Court Decisions Shaping OSHA's Rulemaking Process and OSHA's Approach to Updating Its Permissible Exposure Limits

OSHA's Air Contaminants final rule is the agency's most significant attempt to move away from developing individual, substance-specific standards. As discussed above in Section II, this rule attempted to establish or revise 376 exposure limits for chemicals in a single rulemaking. OSHA's efforts in reducing occupational illnesses and the mortality associated with hazardous chemical exposure has largely been through developing substance specific standards, such as *Hexavalent Chromium* general industry (29 CFR 1910.1026; *Ex. #26*), shipyards (29 CFR 1915.1026), and construction (29 CFR 1926.1026) and *Methylene Chloride* (29 CFR 1910.1052; *Ex. #27*). These standards, in addition to setting PELs, establish other provisions to help reduce risk to workers, such as requirements to monitor exposure, train workers and conduct medical surveillance, if appropriate.

However, due to the associated time and costs, promulgating comprehensive rules for individual chemical hazards is an ineffective approach to address all chemical hazard exposures because of the sheer number of chemicals and mixtures to which workers are exposed on a daily basis. To date, only 30 comprehensive individual standards have been successfully published by the Agency to address hazardous chemicals in the workplace.

The courts have had a significant impact on OSHA's rulemaking process by articulating specific burdens OSHA must meet before promulgating a standard. It was because the *Air Contaminants* court found that OSHA had failed to meet some of these burdens that the court vacated OSHA's attempt to update the PELs. This section discusses the important cases laying out OSHA's burdens under the OSH Act, and summarizes the reasons the *Air Contaminants* court gave for finding that OSHA had not satisfied those burdens. These cases influence what steps OSHA may take in the future to update the PELs.

A. The Substantial Evidence Test: OSHA's Burden of Proof for Promulgating Health Standards

The test used by the courts to determine whether OSHA has reached its burden of proof is the ''substantial evidence test.'' This test, which applies to policy decisions as well as factual determinations, is set forth in section 6(f) of the OSH Act, which states: ''the determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.'' 29 U.S.C. 655(f). ''Substantial evidence'' has been defined as ''such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'' *Cotton Dust,* 452 U.S. at 522; *Ex. #15* (quoting *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 477 (1951) *Ex. #16*).

Although the substantial evidence test requires OSHA to show that the record as a whole supports the final rule, OSHA is not required to wait for ''scientific certainty'' before promulgating a health standard. *Benzene,* 448 U.S. at 656 (*Ex. #10*). Rather, to meet its burden of proof under the ''substantial evidence test,'' the agency need only ''identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument.'' *Lead I,* 647 F.2d. at 1207; *Ex. #12*.

B. The Air Contaminants Case

OSHA published the Air Contaminants final rule on January 19, 1989. As discussed in Section II, the standard adopted more protective PELs for 212 previously regulated substances, set new PELs for 164 previously unregulated substances, left unchanged the PELs for 52 substances for which lower limits had been proposed, and raised the PEL for one substance. 54 FR 2332. The rule was challenged by both industry and labor groups, which both raised a series of issues regarding the validity of the final rule.

The first issue addressed by the court was whether OSHA's ''generic'' approach to rulemaking used to update or create new PELs for 376 chemicals in a single rulemaking was permissible under the OSH Act. Although the Eleventh Circuit determined that the Air Contaminants final rule did not fit within the classic definition of a generic rulemaking, the court upheld the format used by OSHA to update the PELs. *Air Contaminants,* 965 F.2d at 972. The court, in so holding, reasoned ''nothing in the OSH Act prevented OSHA from addressing multiple substances in a single rulemaking.'' *Air Contaminants,* 965 F.2d at 972. The court also upheld OSHA's statutory authority to select the substances and determine the parameters of its rules. However, the court stated that even though OSHA was permitted to promulgate multi-substance rules, each substance was required to ''stand independently, *i.e.,* . . . each PEL must be supported by substantial evidence in the record considered as a whole and accompanied by adequate explanation.'' *Air Contaminants,* 965 F.2d at 972; *Ex. #8*.

C. Significant Risk of a Material Impairment

1. The Benzene Case and Significant Risk

The significant risk requirement was first articulated in 1980 in a plurality decision of the Supreme Court in *Benzene,* 448 U.S. 607. The petitioners in *Benzene* challenged OSHA's rule lowering its PEL for benzene from 10 ppm to 1 ppm. In support of the new PEL, OSHA found that benzene caused leukemia and that the evidence did not show that there was a safe threshold exposure level below which no excess leukemia would occur. Applying its policy to treat carcinogens as posing a risk at any level of exposure where such a threshold could not be established, OSHA chose the new PEL of 1 ppm based on its finding that it was the lowest feasible exposure level. This was because Section 6(b)(5) of the OSH Act requires standards to be set at the most protective level that is feasible. *See Benzene,* 448 U.S. at 633–37; *Ex. #10*.

The *Benzene* Court rejected OSHA's approach. First, it found that the OSH Act did not require employers to ''eliminate all risks of harm from their workplaces.'' The OSH Act defines ''occupational safety and health standard'' to be standard that require the adoption of practices which are ''reasonably necessary or appropriate to provide safe or healthful employment and places of employment''. OSH Act § 3(8), 29 U.S.C. 652(8); *Ex. #9*.

Relying on this definition, the Court found that the Act only required that employers ensure that their workplaces are safe, that is, that their workers are not exposed to ''significant risk[s] of harm.'' 448 U.S. at 642. Second, the Court made clear that it is OSHA's burden to establish that a significant risk is present at the current standard before lowering a PEL. The burden of proof is normally on the proponent, the Court noted, and there was no indication in the OSH Act that Congress intended to change this rule. 448 U.S. at 653, 655. Thus, the Court held that, before promulgating a health standard, OSHA is required to make a ''threshold finding that a place of employment is unsafe– in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' before it can adopt a new standard. *Benzene,* 448 U.S. at 642; *Ex. #10*.

Although the Court declined to establish a set test for determining whether a workplace is unsafe, it did provide guidance on what constitutes a significant risk. The Court stated a significant risk was one that a reasonable person would consider significant and ''take appropriate steps to decrease or eliminate.'' *Benzene,* 448 U.S. at 655 (*Ex. #10*). For example, it said, a one in a 1,000 risk would satisfy the requirement. However, this example was merely an illustration, not a hard line rule. The Court made it clear that determining whether a risk was ''significant'' was not a ''mathematical straitjacket'' and did not require the Agency to calculate the exact probability of harm. 448 U.S. at 655. OSHA was not required to support a significant risk finding ''with anything approaching scientific certainty'' and was free to use ''conservative assumptions'' in interpreting the evidence. 448 U.S. at 656. Still, because OSHA had not made a significant risk finding at the 10 ppm level (indeed, the Court characterized the evidence of leukemia in the record at the 10 ppm level as ''sketch[y]''), the Court vacated the new PEL and remanded the matter to OSHA.

2. OSHA's Post-Benzene Approach to Significant Risk and Air Contaminants

In past rulemakings involving hazardous chemicals, OSHA satisfied its requirement to show that a significant risk of harm is present by estimating the risk to workers subject to a lifetime of exposure at various possible exposure levels. These estimates have typically been based on quantitative risk assessments. As a general policy, OSHA has considered a lifetime excess risk of one death or serious illness per 1000 workers associated with occupational exposure over a 45 year working life as clearly representing a significant risk. However, as noted above, *Benzene* does not require OSHA to use such a rigid or formulaic criterion. Nevertheless, OSHA has taken a conservative approach and has used the 1:1,000 example as a useful benchmark for determining significant risk. This approach has often involved the use of the quantitative risk assessment models OSHA has employed in developing substance-specific health standards.

In the Air Contaminants rule, OSHA departed from this approach. Rather, as noted above, it looked at whether studies showed excess effects of concern at concentrations lower than allowed under OSHA's existing standard. Where they did, OSHA made a significant risk finding and either set a PEL (where none existed previously) or lowered the existing PEL. These new PELs were based on agency judgment, taking into account the existing studies, and as appropriate, safety factors. Both industry and union petitioners challenged aspects of OSHA's approach to making its significant risk determinations. The AFL–CIO argued that OSHA's rule was ''systematically under protective,'' and asserted that 16 of the exposure limits in the final rule were too high. For example, the AFL–CIO argued that OSHA had made a policy determination not to lower the PELs for carbon tetrachloride and vinyl bromide even though the exposure limits chosen

would continue to pose a residual risk in excess of 3.7 deaths per 1,000 workers exposed over the course of their working lifetime. The court agreed with the AFL–CIO, finding that OSHA failed to provide adequate evidence to support the higher PEL chosen by the agency. The court found that some of the PELs chosen by the Agency were at levels that would continue to pose a significant risk of material health impairment, and concluded that OSHA's decision was due to time and resource constraints, rather than legitimate considerations, such as feasibility. *Air Contaminants,* 965 F.2d at 976–77; *Ex. #8.*

Conversely, the American Iron and Steel Institute (AISI; *Ex. #147*) argued that OSHA set the PELs for certain substances below the level substantiated by the evidence. AISI argued that OSHA failed to quantify the risk of material health impairment at present exposure levels posed by individual substances and instead relied on assumptions in order to select its updated PELs. The court agreed with the AISI, finding that although OSHA summarized the studies on health effects in the final rule, it did not explain why the ''studies mandated a particular PEL chosen.'' *Air Contaminants,* 965 F.2d at 976. Specifically, the court stated that OSHA failed to quantify the risk from individual substances and merely provided conclusory statements that the new PEL would reduce a significant risk of material health effects. *Air Contaminants,* 965 F.2d at 975.

OSHA argued to the court that it relied on safety factors in setting PELs. Safety or uncertainty factors are used to ensure that exposure limits for a hazardous substance are set sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees. As explained in the 1989 Air Contaminants rule, regulators use safety factors in this context to account for statistical limitations in studies showing no observed effects, the uncertainties in extrapolating effects observed in animals to humans, and variation in human responses. The size of the proper safety factor is a matter of professional judgment. 54 FR 2397–98

The Eleventh Circuit rejected OSHA's use of safety factors in the Air Contaminants rule, however. While noting that the *Benzene* case held that OSHA is permitted ''to use conservative assumptions in interpreting data . . ., risking error on the side of overprotection rather than under protection,'' *Benzene,* 448 U.S. at 656, the *Air Contaminants* court found that OSHA had not adequately supported the use of safety factors in this rule. The court observed that ''the difference between the level shown by the evidence and the final PEL is sometimes substantial,'' and assumed that though ''it is not expressly stated, that for each of those substances OSHA applied a safety factor to arrive at the final standard.'' 965 F.2d at 978. OSHA had not indicated ''how the existing evidence for individual substances was inadequate to show the extent of risk for these factors,'' and ''failed to explain the method by which its safety factors were determined.'' *Air Contaminants,* 965 F.2d at 978. ''OSHA may use assumptions but only to the extent that those assumptions have some basis in reputable scientific evidence,'' the court concluded. *Air Contaminants,* 965 F.2d at 978–979. See Section IV. A. for additional discussion of the use of safety factors in risk assessment.

Ultimately, although the Eleventh Circuit noted that OSHA ''probably established that most or all of the substances involved do pose a significant risk at some level,'' the court determined that OSHA failed to adequately explain or provide evidence to support its conclusion that ''exposure to these substances at previous levels posed a significant risk . . . or that the new standard eliminates or reduces that risk to the extent feasible.'' *Air Contaminants,* 965 F.2d at 987. Therefore, the court vacated the rule and remanded it to the agency.

3. Material Impairment

Under section 6(b)(5), OSHA must set standards to protect employees against ''material impairment of health or functional capacity.'' This requirement was uncontroversial in *Benzene,* since the effect on which OSHA regulated was leukemia. However, in *Air Contaminants,* AISI argued that not all of the health effects addressed by OSHA in the final rule were material health effects. Specifically, AISI stated that the category of ''sensory irritation,'' which OSHA used as an endpoint to set PELs for 79 substances, failed to distinguish between ''materially impairing sensory irritation and the less serious sort.'' AISI brief at page 24. The court rejected AISI's argument. It accepted OSHA's explanation that material impairments may be any health effect, permanent or transitory, that seriously threatens the health or job performance of an employee, and held that, ''OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment.'' *Air Contaminants,* 965 F.2d at 975. ''Section 6(b)(5) of the [OSH] Act charges OSHA with addressing all forms of 'material impairment of health or functional capacity,'' and not exclusively those causing 'death or serious physical harm' or 'grave danger' from exposure to toxic substances, the court held. *Air Contaminants,* 965 F.2d at 975; *Ex. #8.*

D. Technological and Economic Feasibility

Once OSHA makes its threshold finding that a significant risk is present at the current PEL or in the absence of a PEL and can be reduced or eliminated by a standard, the Agency considers feasibility. First, the feasibility requirement that originated in Section 6(b)(5) of the OSH Act requires that the standard be ''technologically feasible,'' which generally means an industry has to be able to develop the technology necessary to comply with the requirements in the standard. *Lead I,* 647 F.2d at 1264–65; *Ex. #12.*

Second, the standard must be ''economically feasible,'' meaning that an industry as a whole must be able to absorb the impact of the costs associated with compliance with the standard. *Id.* at 1265. OSHA has historically made determinations on technological feasibility and economic feasibility separately.

1. Technological Feasibility

A standard is technologically feasible if ''a typical firm will be able to develop and install engineering and work practice controls that can meet the PEL in most operations.'' *Lead I,* 647 F.2d at 1272. Standards are permitted to be ''technology forcing,'' meaning that OSHA can require industries to ''develop new technology'' or ''impose a standard which only the most technologically advanced plants in an industry have been able to achieve, even if only in some of their operations some of the time.'' *Lead I,* 647 F.2d at 1264; *Ex. #12.*

Technological feasibility analysis generally focuses on demonstrating that PELs can be achieved through engineering and work practice controls. However, the concept of technological feasibility applies to all aspects of the standard, including air monitoring, housekeeping, and respiratory protection requirements. Some courts have required OSHA to determine whether a standard is technologically feasible on an industry-by-industry basis, *Color Pigments Manufacturers Assoc.* v. *OSHA,* 16 F.3d 1157 (*Ex. #13),* 1162–63 (11th Cir. 1994); *Air Contaminants,* 965 F.2d at 981–82 (*Ex. #8),* while another court has upheld technological feasibility findings based on the nature of an activity across many industries rather than on a pure industry basis, *Public Citizen Health Research Group* v. *United States Department of Labor,* 557 F.3d 165,178–79 (3d Cir. 2009; *Ex. #14*).

Regardless, OSHA must show the existence of ''technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines,'' *Lead I,* 647 F.2d 1272. Where the agency presents ''substantial evidence that companies acting vigorously and in good faith can develop the technology,'' the agency is not bound to the technological status quo, and ''can require industry to meet PELs never attained anywhere.'' *Lead I,* 647 F.2d 1265; *Ex. #12.*

OSHA usually demonstrates the technological feasibility of a PEL by finding establishments in which the PEL is already being met and identifying the controls in use, or by arguing that even if the PEL is not currently being met in a given operation, the PEL could be met with specific additional controls. OSHA is also concerned with determining whether the conditions under which the PEL can be met in specific plants are generalizable to an industry as whole. This approach is very resource-intensive, as it commonly requires gathering detailed information on exposure levels and controls for each affected operation and process in an industry. OSHA's inspection databases usually do not record this information, and consequently OSHA makes site visits for the specific purpose of determining technological feasibility. (See Section IV. of this Request for Information for a detailed discussion of how OSHA determines technological feasibility and possible alternatives to current methods.)

As noted above, in the Air Contaminants rule, OSHA made its feasibility determination by gathering information on work processes that might expose workers

above the new PELs, and identifying controls that had been successfully implemented to reduce the exposure to the new limits. It made these findings mainly at the two-digit SIC level, but also at the three- and four-digit level where appropriate given the processes involved. The *Air Contaminants* court rejected this approach, finding that OSHA failed to make industry-specific findings or identify the specific technologies capable of meeting the proposed limit in industry-specific operations. *Air Contaminants,* 965 F.2d at 981. While OSHA had identified primary air contaminant control methods: engineering controls, administrative controls and work practices and personal protective equipment, the agency, ''only provided a general description of how the generic engineering controls might be used in the given sector.'' *Air Contaminants,* 965 F.2d at 981. Though noting that OSHA need only provide evidence sufficient to justify a ''general presumption of feasibility,'' the court held that this ''does not grant OSHA license to make overbroad generalities as to feasibility or to group large categories of industries together without some explanation of why findings for the group adequately represents the different industries in that group.'' *Air Contaminants,* 965 F.2d at 981–82. Accordingly, the court held that OSHA failed to establish the technological feasibility of the new PELs in its final rule. *Air Contaminants,* 965 F.2d at 982. As noted below, in a subsequent rulemaking the reviewing court accepted OSHA's approach of grouping numbers of industries.

2. Economic Feasibility

With respect to economic feasibility, the courts have stated ''A standard is feasible if it does not threaten ''massive dislocation'' to . . . or imperil the existence of the industry.'' *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1265 (D.C. Cir. 1980) *Lead I,*). In order to show this, the same court suggested, OSHA should ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry.'' The same court noted, ''[T]he court probably cannot expect hard and precise estimates of costs. Nevertheless, the agency must of course provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry.'' *Lead I,* 647 F.2d at 1265; *Ex. #12.*

Economic feasibility does not entail a cost-benefit analysis of the level of protection provided by the standard. As the Supreme Court noted, Congress considered the costs of creating a safe and healthful workplace to be the cost of doing business. *Cotton Dust,* 452 U.S. at 514, 520; *Ex. #15.* Instead, standards are economically feasible if the standard will not substantially alter the industry's competitive structure. *Forging Indus. Ass'n* v. *Secretary of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985; *Ex. #148*). In order to make a determination of economic feasibility, OSHA should ''construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry,'' *Lead I,* 647 F.2d at 1272, noting that such analyses will not provide absolute certainty:

[T]he court probably cannot expect hard and precise estimates of costs. Nevertheless, the agency must of course provide a reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry . . . . And OSHA can revise any gloomy forecast that estimated costs will imperil an industry by allowing for the industry's demonstrated ability to pass through costs to consumers. 647 F.2d at 1266–67.

Again, courts have required OSHA to determine whether a standard is economically feasible on an industry-by-industry basis. *See Air Contaminants,* 965 F.2d at 982 (*Ex. #8*). Both to meet requirements for any Regulatory Flexibility Act (5 U.S.C. 603, 604) analysis and to assure that standards do not threaten the competitive structure of an industry, OSHA also analyzes the economic impacts on different size classes within an industry. However, OSHA is not required to show that all companies within an industry will be able to bear the burden of compliance or ''guarantee the continued existence of individual employers.'' *Lead I,* 647 F.2d at 1265 (*Ex. #12*) (quoting *Industrial Union Dep't, AFL–CIO* v. *Hodgson,* 499 F.2d 467, 478 (D.C. Cir. 1974) *Ex. #55)*).

As discussed above, OSHA supported its economic feasibility findings for the 1989 Air Contaminants rule based primarily on the results of a survey of over 5700 businesses, summarizing the projected cost of compliance at the two-digit SIC industry sector level. It found that compliance costs would average less than one percent of profits, and, alternatively, that prices would increase by less than one half percent. Nonetheless, the Eleventh Circuit held that OSHA had failed to meet its burden. The court held that OSHA was required to show that the rule was economically feasible on an industry-by industry basis, and that OSHA had not shown that its analyses at the two-digit SIC industry sector level were appropriate to meet this burden. *Air Contaminants,* 965 F.2d at 982. OSHA argued the generic nature of the rulemaking allowed the agency ''a great latitude in grouping industries in order to estimate 'average' costs,'' and that ''the costs were sufficiently low per sector to demonstrate feasibility not only for each sector, but each sub-sector.'' *Air Contaminants,* 965 F.2d at 983. However, the court found that ''average estimates of cost can be extremely misleading in assessing the impact of particular standards on individual industries'' and observed that ''analyzing the economic impact for an entire sector could conceal particular industries laboring under special disabilities and likely to fail as a result of enforcement.'' *Air Contaminants,* 965 F.2d at 982. The court allowed that OSHA could ''find and explain that certain impacts and standards do apply to entire sectors of an industry'' if ''coupled with a showing that there are no disproportionately affected industries within the group.'' *Air Contaminants,* 965 F.2d at 982 n.28. But in this case, the court found, OSHA had not explained why its use of such a ''broad grouping was appropriate.'' *Air Contaminants,* 965 F.2d at 983; *Ex. #8.*

Ultimately, the court held that OSHA did not sufficiently explain or support its threshold determination that exposures above the new PELs posed significant risks of material health impairment, or that the new PELs eliminated or reduced the risks to the extent feasible. Finding that ''OSHA's overall approach to this rulemaking is . . . flawed,'' the court vacated the entire Air Contaminant rulemaking, rather than just the 23 chemicals that were contested by union and industry representatives. *Air Contaminants,* 965 F.2d at 987(*Ex. #8*).

The Eleventh Circuit denied OSHA's petition for rehearing. No longer having a basis to enforce the 1989 PELs, OSHA directed its compliance officers to stop enforcing the updated limits through a memo, which was followed by a **Federal Register** Notice on June 30, 1993, revoking the new limits. 58 FR 35338–35351; (*Ex. #19*).

Appendix B: 1989 PELs Table

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Acetaldehyde	75–07–0	100	180	150	270			
Acetic acid	64–19–7	10	25					
Acetic anhydride	108–24–7					5	20	
Acetone	67–64–1	750	1800	1000	24006			
Acetonitrile	75–05–8	40	70	60	105			
2-Acetylamino-fluorine; see 1910.1014	53–96–3.							
Acetylene dichloride; see 1,2-Dichloroethylene	540–59–0.							
Acetylene tetrabromide	79–27–6	1	14					
Acetylsalicylic acid (Aspirin)	50–78–2		5					
Acrolein	107–02–8	0.1	0.25	0.3	0.8			
Acrylamide	79–06–1		0.03					X

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Acrylic acid	79–10–7	10	30					X
Acrylonitrile; see 1910.1045	107–13–1							
Aldrin	309–00–2		0.25					X
Allyl alcohol	107–18–6	2	5	4	10			X
Allyl chloride	107–05–1	1	3	2	6			
Allyl glycidyl ether (AGE)	106–92–3	5	22	10	44			
Allyl propyl disulfide	2179–59–1	2	12	3	18			
alpha-Alumina	1344–28–1							
	Total dust		10					
	Respirable fraction		5					
Aluminum (as Al) Metal	7429–90–5.							
	Total dust		15					
	Respirable fraction		5					
	Pyro powders		5					
	Welding fumes		5					
	Soluble salts		2					
	Alkyls		2					
4-Aminodiphenyl; see 1910.1011	92–67–1.							
2-Aminoethanol; see Ethanolamine	141–43–5.							
2-Aminopyridine	504–29–0	0.5	2					
Amitrole	61–82–5		0.2					
Ammonia	7664–41–7			35	27			
Ammonium chloride fume	12125–02–9		10		20			
Ammonium sulfamate	7773–06–0.							
	Total dust		10					
	Respirable fraction		5					
n-Amyl acetate	628–63–7	100	525					
Sec-Amyl acetate	626–38–0	125	650					
Aniline and homologs	62–53–3	2	8					X
Anisidine (o-, p-isomers)	29191–52–4		0.5					
Antimony and compounds (as Sb)	7440–36–0		0.5					
ANTU (alpha naphthyl-thiourea)	86–88–4		0.3					
Arsenic, organic compounds (as As)	7440–38–2		0.5					
Arsenic, inorganic compounds (as As); see 1910.1018	Varies with compound.							
Arsine	7784–42–1	0.05	0.2					
Asbestos; see 1910.1001	Varies							
Atrazine	1912–24–9		5					
Azinphos-methyl	86–50–0		0.2					X
Barium, soluble compounds	7440–39–3		0.5					
Barium sulfate	7727–43–7.							
	Total dust		10					
	Respirable fraction		5					
Benomyl	17804–35–2.							
	Total dust		10					
	Respirable fraction		5					
Benzene; see 1910.1028. See Table Z–2 for the limits applicable in the operations or sectors excluded in 1910.1028.	71–43–2.							
Benzidine; see 1910.1010	92–87–5.							
p-Benzoquinone; see Quinone	106–51–4.							
Benzo(a)pyrene; see Coal tar pitch volatiles								
Benzoyl peroxide	94–36–0		5					
Benzyl chloride	100–44–7	1	5					
Beryllium and beryllium compounds (as Be)	7440–41–7	0.002		[1].005		0.025		
Biphenyl; see Diphenyl	92–52–4.							
Bismuth telluride, undoped	1304–82–1.							
	Total dust		15					
	Respirable fraction		5					
Bismuth telluride, Se-doped	1304–82–1		5					
Borates, tetra, sodium salts:								
Anhydrous	1330–43–4			10				
Decahydrate	1303–96–4			10				
Penta-hydrate	12179–04–3			10				
Boron oxide	1303–86–2.							
	Total dust		10					
	Respirable Fraction.		5					
Boron tribromide	10294–33–4					1	10	
Boron trifluoride	7637–07–2					1	3	
Bromacil	314–40–9	1	10					
Bromine	7726–95–6	0.1	0.7	0.3	2			
Bromine pentafluoride	7789–30–2	0.1	0.7					
Bromoform	75–25–2	0.5	5					X
Butadiene (1,3- Butadiene); see 1910.1051	106–99–0.							
Butane	106–97–8	800	1900					
Butanethiol; see Butyl mercaptan	109–79–5.							
2-Butanone (Methyl ethyl ketone)	78–93–3	200	590	300	885			

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
2-Butoxyethanol	111–76–2	25	120					X
n-Butyl-acetate	123–86–4	150	710	200	950			
sec-Butyl acetate	105–46–4	200	950					
tert-Butyl acetate	540–88–5	200	950					
Butyl acrylate	141–32–2	10	55					
n-Butyl alcohol	71–36–3					50	150	X
sec-Butyl alcohol	78–92–2	100	305					
tert-Butyl alcohol	75–65–0	100	300	150	450			
Butylamine	109–73–9					5	15	X
tert-Butyl Chromate (as CrO3)	1189–85–1						0.1	X
n-Butyl glycidyl ether (BGE)	2426–08–6	25	135					
n-Butyl lactate	138–22–7	5	25					
Butyl mercaptan	109–79–5	0.5	1.5					
o-sec-Butylphenol	89–72–5	5	30					X
p-tert-Butyltoluene	98–51–1	10	60	20	120			
Cadmium (all forms, as Cd); see 1910.1027 See Table Z–2 for the limits applicable in the operations or sectors excluded in 1910.1027.	7440–43–9.							
Calcium carbonate	1317–65–3.							
	Total dust		15					
	Respirable fraction		5					
Calcium cyanamide	156–62–7		0.5					
Calcium hydroxide; see particulates not otherwise regulated.	1305–62–0		5					
Calcium oxide	1305–78–8		5					
Calcium silicate	1344–95–2							
	Total dust		15					
	Respirable fraction		5					
Calcium sulfate	7778–18–9.							
	Total dust		15					
	Respirable fraction		5					
Camphor, synthetic	76–22–2.							
Camphor, synthetic	76–22–2		2					
Caprolactam	105–60–2.							
	Dust		1		3			
	Vapor	5	20	10	40			
Captafol (Difolatan®)	2425–06–1		0.1					
Captan	133–06–2		5					
Carbaryl (Sevin®)	63–25–2		5					
Carbofuran (Furadan®)	1563–66–2		0.1					
Carbon black	1333–86–4		3.5					
Carbon dioxide	124–38–9	10,000	18,000	30,000	54,000			
				0	0			
Carbon disulfide	75–15–0	4	12	12	36			X
Carbon monoxide	630–08–0	35	40			200	229	
Carbon tetrabromide	558–13–4	0.1	1.4	0.3	4			
Carbon tetrachloride	56–23–5	2	12.6					
Carbonyl fluoride	353–50–4	2	5	5	15			
Catechol (Pyrocatechol)	120–80–9	5	20					X
Cellulose	9004–34–6.							
	Total dust		15					
	Respirable fraction		5					
Cesium hydroxide	21351–79–1		2					
Chlordane	57–74–9		0.5					X
Chlorinated camphene	8001–35–2		0.5		1			X
Chlorinated diphenyl oxide	55720–99–5		0.5					
Chlorine	7782–50–5	0.5	1.5	1	3			
Chlorine dioxide	10049–04–4	0.1	0.3	0.3	0.9			
Chlorine trifluoride	7790–91–2					0.1	0.4	
Chloro-acetaldehyde	107–20–0					1	3	
alpha-Chloroaceto-phenone (Phenacy1 chloride)	532–27–4	0.05	0.3					
Chloroacetyl chloride	79–04–9	0.05	0.2					
Chlorobenzene	108–90–7	75	350					
o-Chloro-benzylidene malononitrile	2698–41–1					0.05	0.4	X
Chloro-bromomethane	74–97–5	200	1050					
2-Chloro-1,3-butadiene; see beta-Chloroprene	126–99–8							
Chloro-difluoromethane	75–45–6	1000	3500					
Chlorodiphenyl (42% Chlorine) (PCB)	53469–21–9		1					X
Chlorodiphenyl (54% Chlorine) (PCB)	11097–69–1		0.5					X
1-Chloro,2,3-epoxypropane; see Epichlorohydrin	106–89–8.							
2-Chloroethanol; see Ethylene chlorohydrin	107–07–3.							
Chloroethylene; see Vinyl chloride	75–01–4.							
Chloroform (Trichloro-methane)	67–66–3	2	9.78					
bis(Chloro-methyl) ether; see 1910.1008	542–88–1.							
Chloromethyl methyl ether; see 1910.1006	107–30–2.							
1-Chloro-l-nitropropane	600–25–9	2	10					
Chloropenta-fluoroethane	76–15–3	1000	6320					
Chloropicrin	76–06–2	0.1	0.7					

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
beta-Chloroprene	126–99–8	10	35					X
o-Chlorostyrene	2039–87–4	50	285	75	428			
o-Chlorotoluene	95–49–8	50	250					
2-Chloro-6-trichloro-methyl pyridine	1929–82–4.							
	Total dust		15					
	Respirable fraction		5					
Chlorpyrifos	2921–88–2		0.2					X
Chromic acid and chromates (as CrO3); see 1910.1026. See Table Z–2 for the exposure limit for any operations or sectors where the exposure limit in 1910.1026 is stayed or are otherwise not in effect.	Varies with compound.					0.1		
Chromium (II) compounds (as Cr)	Varies with compound.		0.5					
Chromium (III) compounds (as Cr)	Varies with compound.		0.5					
Chromium metal and insoluble salts	7440–47–3		1					
Chrysene; see Coal tar pitch volatiles								
Clopidol	2971–90–6.							
	Total dust		15					
	Respirable fraction		5					
Coal dust (less than 5% Si02), quartz, respirable fraction	N/A		2					
Coal dust (greater than or equal to 5% Si02) respirable quartz fraction.	N/A		0.1					
Coal tar pitch volatiles (benzene soluble fraction), anthracene, BaP, phenanthrene, acridine, chrysene, pyrene.	8007–45–2		0.2					
Cobalt metal, dust, and fume (as Co)	7440–48–4		0.05					
Cobalt carbonyl (as Co)	10210–68–1		0.1					
Cobalt hydrocarbonyl (as Co)	16842–03–8		0.1					
Coke oven emissions; See 1910.1029								
Copper	7440–50–8.							
	Fume (as Cu)		0.1					
	Dusts and mists (as Cu).		1					
Cotton dust, raw This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust or equivalent instrument. The time-weighted average applies to the cotton waste processing operations of waster recycling (sorting, blending, cleaning, and willowing) and garnetting. See also 1910.1043 for cotton dust limits applicable to other sectors.								
Crag herbicide (Sesone)	136–78–7.							
	Total dust		10					
	Respirable fraction		5					
Cresol, all isomers	1319–77–3; 95–48–7; 108–39–4; 106–44–5.	5	22					X
Crotonaldehyde	123–73–9; 4170–30–3.		2	6				
Crufomate	106–44–5		5					
Cumene	98–82–8	50	245					X
Cyanamide	420–04–2		2					
Cyanides (as CN)	151–50–0		5					
Cyanogen	460–19–5	10	20					
Cyanogen chloride	506–77–4					0.3	0.6	
Cyclohexane	110–82–7	300	1050					
Cyclohexanol	108–93–0	50	200					X
Cyclohexanone	108–94–1	25	100					X
Cyclohexene	110–83–8	300	1015					
Cyclohexylamine	108–91–8	10	40					
Cyclonite	121–82–4		1.5					X
Cyclopentadiene	542–92–7	75	200					
Cyclopentane	287–92–3	600	1720					
Cyhexatin	13121–70–5		5					
2,4–D (Dichlorophenoxy-acetic acid)	94–75–7		10					
Decaborane	17702–41–9	0.05	0.3	0.15	0.9			X
Demeton-(Systox®)	8065–48–3		0.1					X
Diborane	19207–45–7	0.1	0.1					
Dichlorodiphenyltri-chloroethane (DDT)	50–29–3		1					X
Dichlorvos (DDVP)	62–73–7		1					X
Diacetone alcohol (4-Hydroxy-4-methyl-2-pentanone)	123–42–2	50	240					
1,2-Diaminoethane; see Ethylenediamine	107–15–3.							
Diazinon	333–41–5		0.1					X
Diazomethane	334–88–3	0.2	0.4					
1,2-Dibromo-3-chloropropane; see 1910.1044	96–12–8.							
2–N-Dibutylamino-ethanol	102–81–8	2	14					
Dibutyl phosphate	107–66–4	1	5	2	10			
Dibutyl phthalate	84–74–2		5					
Dichloro-acetylene	7572–29–4					0.1	0.4	

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
o-Dichlorobenzene	95–50–1					50	300	
p-Dichlorobenzene	106–46–7	75	450	110	675			
3,3′-Dichloro-benzidine; see 1910.1007	91–94–1.							
Dichlorodifluoro-methane	75–71–8	1000	4950					
1,3-Dichloro-5,5-dimethyl hydantoin	118–52–5		0.2		0.4			
1,1-Dichloroethane	75–34–3	100	400					
1,2-Dichloroethylene	540–59–0	200	790					
Dichloroethyl ether	111–44–4	5	30	10	60			X
Dichloro-methane; see Methylene chloride	75–09–2.							
Dichloromono-fluoromethane	75–43–4	10	40					
1,1-Dichloro- 1-nitroethane	594–72–9	2	10					
1,2-Dichloropropane; see Propylene dichloride	78–87–5.							
1,3-Dichloropropene	542–75–6	1	5					X
2,2-Dichloro-propionic acid	75–99–0	1	6					
Dichloro-tetrafluoroethane	76–14–2	1000	7000					
Dicrotophos	141–66–2		0.25					X
Dicyclo-pentadiene	77–73–6	5	30					
Dicyclo-pentadienyl iron	102–54–5.							
	Total dust		10					
	Respirable fraction		5					
Dieldrin	60–57–1		0.25					X
Diethanolamine	111–42–2	3	15					
Diethylamine	109–89–7	10	30	25	75			
2-Diethylamino-ethanol	100–37–8	10	50					
Diethylene triamine	111–40–0	1	4					
Diethyl ether; see Ethyl ether	60–29–7.							
Diethyl ketone	96–22–0	200	705					
Diethyl phthalate	84–66–2		5					
Difluorodibromo-methane	75–61–6	100	860					
Diglycidyl ether (DGE)	2238–07–5	0.1	0.5					
Dihydroxy-benzene; see Hydroquinone	123–31–9.							
Diisobutyl ketone	108–83–8	25	150					
Diisopropylamine	108–18–9	5	20					X
4-Dimethylamino-azobenzene; see 1910.1015	60–11–7.							
Dimethoxy-methane; see Methylal	109–87–5.							
Dimethyl acetamide	127–19–5	10	35					X
Dimethylamine	124–40–3	10	18					
Dimethylamino-benzene; see Xylidine	1300–73–8.							
Dimethylaniline (N,N-Dimethylaniline)	121–69–7	5	25	10	50			X
Dimethyl-benzene; see Xylene	Varies with isomer.							
Dimethyl-1,2-dibromo-2,2-dichloroethyl phosphate	300–76–5		3					X
Dimethyl-formamide	68–12–2	10	30					X
2,6-Dimethyl-4-heptanone; see Diisobutyl ketone	108–83–8.							
1,1-Dimethyl-hydrazine	57–14–7	0.5	1					X
Dimethyl-phthalate	131–11–3		5					
Dimethyl sulfate	77–78–1	0.1	0.5					X
Dinitolmide (3,5-Dinitro-o-toluamide)	148–01–6		5					
Dinitrobenzene (all isomers)	(alpha): 528–29–0 (meta): 99–65–0. (para-): 100–25–4.		1					X
Dinitro-o-cresol	534–52–1		0.2					X
Dinitrotoluene	121–14–2		1.5					X
Dioxane (Diethylene dioxide)	123–91–1	25	90					X
Dioxathion (Delnav)	78–34–2		0.2					X
Diphenyl (Biphenyl)	92–52–4	0.2	1					
Diphenylamine	122–39–4		10					
Diphenylmethane diisocyanate; see Methylene bisphenyl isocyanate.	101–68–8.							
Dipropylene glycol methyl ether	34590–94–8	100	600	150	900			X
Dipropyl ketone	123–19–3	50	235					
Diquat	85–00–7		0.5					
Di-sec octyl phthalate (Di-2-ethylhexyl phthalate)	117–81–7		5		10			
Disulfiram	97–77–8		2					
Disulfoton	298–04–4		0.1					X
2,6-Di-tert-butyl-p-cresol	128–37–0		10					
Diuron	330–54–1		10					
Divinyl benzene	108–576	10	50					
Emery	112–62–9.							
	Total dust		10					
	Respirable fraction		5					
Endosulfan	115–29–7		0.1					X
Endrin	72–20–8		0.1					X
Epichlorohydrin	106–89–8	2	8					X
EPN	2104–64–5		0.5					X
1,2-Epoxypropane; see Propylene oxide	75–56–9.							
2,3-Epoxy-l-propanol; see Glycidol	556–52–5.							
Ethanethiol; see Ethyl mercaptan	75–08–1.							
Ethanolamine	141–43–5	3	8	6	15			

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Ethion	563–12–2		0.4					X
2-Ethoxyethanol [In Process of 6(b) Rulemaking]	110–80–5.							
2-Ethoxyethyl acetate (Cellosolve acetate) [In Process of 6(b) Rulemaking].	111–15–9.							
Ethyl acetate	141–78–6	400	1400					
Ethyl acrylate	140–88–5	5	20	25	100			X
Ethyl alcohol (Ethanol)	64–17–5	1000	1900					
Ethylamine	75–04–7	10	18					
Ethyl amyl ketone (5-Methyl-3-heptanone)	106–68–3	25	130					
Ethyl benzene	100–41–4	100	435	125	545			
Ethyl bromide	74–96–4	200	890	250	1110			
Ethyl butyl ketone (3-Heptanone)	106–35–4	50	230					
Ethyl chloride	75–00–3	1000	2600					
Ethyl ether	60–29–7	400	1200	500	1500			
Ethyl formate	109–94–4	100	300					
Ethyl mercaptan	75–08–1	0.5	1					
Ethyl silicate	78–10–4	10	85					
Ethylene chlorohydrin	107–07–3					1	3	X
Ethylenediamine	107–15–3	10	25					
Ethylene dibromide; see Table Z–2	106–93–4.							
Ethylene dichloride	107–06–2	1	4	2	8			
Ethylene glycol	107–21–1					50	125	
Ethylene glycol dinitrate	628–96–6				0.1			X
Ethylene glycol methyl acetate; see Methyl cellosolve acetate.	110–49–6.							
Ethyleneimine; see 1910.1012	151–56–4.							
Ethylene oxide; see 1910.1047	75–21–8.							
Ethylidene chloride; see 1,1-Dichloroethane	75–34–3.							
Ethylidene norbornene	16219–75–3					5	25	
N-Ethylmorpholine	100–74–3	5	23					X
Fenamiphos	22224–92–6		0.1					X
Fensulfothion (Dasanit)	115–90–2		0.1					
Fenthion	55–38–9		0.2					X
Ferbam	14484–64–1.							
	Total dust		10					
	Respirable fraction		5					
Ferrovanadium dust	12604–58–9		1		3			
Fluorides (as F)	Varies with compound.		2.5					
Fluorine	7782–41–4	0.1	0.2					
Fluoro-trichloromethane (Trichlorofluoro-methane)	75–69–4					1000	5600	
Fonofos	944–22–9		0.1					X
Formaldehyde; see 1910.1048	50–00–0.							
Formamide	75–12–7	20	30	30	45			
Formic acid	64–18–6	5	9					
Furfural	98–01–1	2	8					X
Furfuryl alcohol	98–00–0	10	40	15	60			X
Gasoline	8006–61–9	300	900	500	1500			
Gemanium tetrahydride	7782–65–2	0.2	0.6					
Glutaraldehyde	111–30–8					0.2	0.8	
Glycerin (mist)	56–81–5.							
	Total dust		10					
	Respirable fraction		5					
Glycidol	556–52–5	25	75					
Glycol monoethyl ether; see 2-Ethoxyethanol	110–80–5.							
Grain dust (oat, wheat, barley)	N/A		10					
Graphite, natural respirable dust	7782–42–5		2.5					
Graphite, synthetic	N/A.							
	Total dust		10					
	Respirable fraction		5					
Guthion®; see Azinphos methyl	86–50–0.							
Gypsum	7778–18–9.							
	Total dust		15					
	Respirable fraction		5					
Hafnium	7440–58–6		0.5					
Heptachlor	76–44–8		0.5					X
Heptane (n-Heptane)	142–82–5	400	1600	500	2000			
Hexachloro-butadiene	87–68–3	0.02	0.24					
Hexachlorocyclo-pentadiene	77–47–4	0.01	0.1					
Hexa-chloroethane	67–72–1	1	10					X
Hexachloro-naphthalene	1335–87–1		0.2					X
Hexafluoro-acetone	684–16–2	0.1	0.7					X
n-Hexane	110–54–3	50	180					
Hexane isomers	Varies with compound.	500	1800	1000	3600			
2-Hexanone (Methyl n-butyl ketone)	591–78–6	5	20					
Hexone (Methyl isobutyl ketone)	108–10–1	50	205	75	300			
sec-Hexyl acetate	108–84–9	50	300					

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Hexylene glycol	107–41–5					25	125	
Hydrazine	302–01–2	0.1	0.1					X
Hydrogenated terphenyls	61788–32–7	0.5	5					
Hydrogen bromide	10035–10–6					3	10	
Hydrogen chloride	7647–01–0					5	7	
Hydrogen cyanide	74–90–8			4.7	5			X
Hydrogen fluoride (as F)	7664–39–3	3		6				
Hydrogen peroxide	7722–84–1	1	1.4					
Hydrogen selenide (as Se)	7783–07–5	0.05	0.2					
Hydrogen sulfide	7783–06–4	10	14	15	21			
Hydroquinone	123–31–9		2					
2-Hydroxypropyl acrylate	999–61–1	0.5	3					X
Indene	95–13–6	10	45					
Indium and compounds (as In)	7440–74–6		0.1					
Iodine	7553–56–2					0.1	1	
Iodoform	75–47–8	0.6	10					
Iron oxide (dust and fume as Fe) Total particulate	1309–37–1		10					
Iron pentacarbonyl (as Fe)	13463–40–6	0.1	0.8	0.2	1.6			
Iron salts (soluble) (as Fe)	Varies with compound.		1					
Isoamyl acetate	123–92–2	100	525					
Isoamyl alcohol (primary and secondary)	123–51–3	100	360	125	450			
Isobutyl acetate	110–19–0	150	700					
Isobutyl alcohol	78–83–1	50	150					
Isooctyl alcohol	26952–21–6	50	270					X
Isophorone	78–59–1	4	23					
Isophorone diisocyanate	4098–71–9	0.005		0.02				X
2-Isopropoxy-ethanol	109–59–1	25	105					
Isopropyl acetate	108–21–4	250	950	310	1185			
Isopropyl alcohol	67–63–0	400	980	500	1225			
Isopropylamine	75–31–0	5	12	10	24			
N-Isopropylaniline	768–52–5	2	10					X
Isopropyl ether	108–20–3	500	2100					
Isopropyl glycidyl ether (IGE)	4016–14–2	50	240	75	360			
Kaolin	N/A.							
	Total dust		10					
	Respirable fraction		5					
Ketene	463–51–4	0.5	0.9	1.5	3			
Lead inorganic (as Pb); see 1910.1025	7439–92–1.							
Limestone	1317–65–3.							
	Total dust		15					
	Respirable fraction		5					
Lindane	58–89–9		0.5					X
Lithium hydride	7580–67–8		0.025					
L.P.G. (Liquefied petroleum gas)	68476–85–7	1000	1800					
Magnesite	546–93–0.							
	Total dust		15					
	Respirable fraction		5					
Magnesium oxide fume, total particulate	1309–48–4.							
	Total dust		10					
	Respirable fraction		5					
Malathion	121–75–5.							
	Total dust		10					X
	Respirable fraction		5					X
Maleic anhydride	108–31–6	0.25	1					
Manganese compounds (as Mn)	7439–96–5						5	
Manganese fume (as Mn)	7439–96–5		1		3			
Manganese cyclopentadienyl tricarbonyl (as Mn)	12079–65–1		0.1					X
Manganese tetroxide (as Mn)	1317–35–7		1					
Marble	1317–65–3.							
	Total dust		15					
	Respirable fraction		5					
Mercury (aryl and inorganic) (as Hg)	7439–97–6						0.1	X
Mercury (organo) alkyl compounds (as Hg)	7439–97–6		0.01		0.03			X
Mercury (vapor) (as Hg)	7439–97–6		0.05					X
Mesityl oxide	141–79–7	15	60	25	100			
Methacrylic acid	79–41–4	20	70					X
Methanethiol; see Methyl mercaptan	74–93–1.							
Methomyl (Lannate)	16752–77–5		2.5					
Methoxychlor	72–43–5.							
	Total dust		10					
	Respirable fraction		5					
2-Methoxyethanol; see Methyl cellosolve	109–86–4.							
4-Methoxyphenol	150–76–5		5					
Methyl acetate	79–20–9	200	610	250	760			
Methyl acetylene (Propyne)	74–99–7	1000	1650					
Methyl acetylene-propadiene mixture (MAPP)		1000	1800	1250	2250			
Methyl acrylate	96–33–3	10	35					X

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Methyl-acrylonitrile	126–98–7	1	3					X
Methylal (Dimethoxy-methane)	109–87–5	1000	3100					
Methyl alcohol	67–56–1	200	260	250	325			X
Methylamine	74–89–5	10	12					
Methyl amyl alcohol; see Methyl isobutyl carbinol	108–11–2.							
Methyl n-amyl ketone	110–43–0	100	465					
Methyl bromide	74–83–9	5	20					X
Methyl butyl ketone; see 2-Hexanone	591–78–6.							
Methyl cellosolve (2-Methoxyethanol)	109–86–4	25	80					X
Methyl cellosolve acetate (2-Methoxyethyl acetate)	110–49–6	25	120					X
Methyl chloride	74–87–3	50	105	100	210			
Methyl chloroform (1,1,1-Trichloroethane)	71–55–6	350	1900	450	2450			
Methyl 2-cyanoacrylate	137–05–3	2	8	4	16			
Methyl cyclohexane	108–87–2	400	1600					
Methyl-cyclohexanol	25639–42–3	50	235					
o-Methylcyclo-hexanone	583–60–8	50	230	75	345			X
Methylcyclo-pentadienyl manganese tricarbonyl (as Mn)	12108–13–3		0.2					X
Methyl demeton	8022–00–2		0.5					X
4,4′-Methylene bis(2-chloroaniline) (MBOCA)	101–14–4	0.02	0.22					X
Methylene bis(4-cyclo-hexylisocyanate)	5124–30–1					0.01	0.11	X
Methylene chloride; see 1910.1052	75–09–2.							
Methylene-dianiline; see 1910.1050	101–77–9.							
Methyl ethyl ketone peroxide (MEKP)	1338–23–4					0.7	5	
Methyl formate	107–31–3	100	250	150	375			
Methyl hydrazine (Monomethyl hydrazine)	60–34–4					0.2	0.35	X
Methyl iodide	74–88–4	2	10					X
Methyl isoamyl ketone	110–12–3	50	240					
Methyl isobutyl carbinol	108–11–2	25	100	40	165			X
Methyl isobutyl ketone; see Hexone	108–10–1.							
Methyl isocyanate	624–83–9	0.02	0.05					X
Methyl isopropyl ketone	563–80–4	200	705					
Methyl mercaptan	74–93–1	0.5	1					
Methyl methacrylate	80–62–6	100	410					
Methyl parathion	298–00–0		0.2					X
Methyl propyl ketone; see 2-Pentanone	107–87–9.							
Methyl silicate	681–84–5	1	6					
alpha-Methyl styrene	98–83–9	50	240	100	485			
Methylene bisphenyl isocyanate (MDI)	101–68–8					0.02	0.2	
Metribuzin	21087–64–9		5					
Mica; see Silicates	N/A.							
Molybdenum (as Mo)	7439–98–7.							
	Soluble compounds.		5					
	Insoluble compounds total dust.		10					
	Insoluble compounds. Respirable fraction		5					
Monocrotophos (Azodrin)	6923–22–4		0.25					
Monomethyl aniline	100–61–8	0.5	2					X
Morpholine	110–91–8	20	70	30	105			X
Naphtha (Coal tar)	8030–30–6	100	400					
Naphthalene	91–20–3	10	50	15	75			
alpha-Naphthylamine; see 1910.1004	134–32–7.							
beta-Naphthylamine; see 1910.1009	91–59–8.							
Nickel carbonyl (as Ni)	13463–39–3	0.001	0.007					
Nickel, metal and insoluble compounds (as Ni)	7440–02–0		1					
Nickel, soluble compounds (as Ni)	7440–02–0		0.1					
Nicotine	54–11–5		0.5					X
Nitric acid	7697–37–2	*2*	5	4	10			
Nitric oxide	10102–43–9	25	30					
p-Nitroaniline	100–01–6		3					X
Nitrobenzene	98–95–3	1	5					X
p-Nitrochloro-benzene	100–00–5		1					X
4-Nitrodiphenyl; see 1910.1003	92–93–3.							
Nitroethane	79–24–3	100	310					
Nitrogen dioxide	10102–44–0			1	1.8			
Nitrogen trifluoride	7783–54–2	10	29					
Nitroglycerin	55–63–0				0.11			X
Nitromethane	75–52–5	100	250					
1-Nitropropane	108–03–2	25	90					
2-Nitropropane	79–46–9	10	35					
N-Nitrosodimethyl-amine; see 1910.1016	62–75–9.							
Nitrotoluene	o-isomer 88–72–2 m-isomer 99–08–1 p-isomer 99–99–0.	2	11					X
Nitrotrichloro-methane; see Chloropicrin	76–06–2.							

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Nonane	111–84–2	200	1050					
Octachloro-naphthalene	2234–13–1		0.1		0.3			X
Octane	111–65–9	300	1450	375	1800			
Oil mist, mineral	8012–95–1		5					
Osmium tetroxide (as Os)	20816–12–0	0.0002	0.002	0.0006	0.006			
Oxalic acid	144–62–7		1		2			
Oxygen difluoride	7783–41–7					0.05	0.1	
Ozone	10028–15–6	0.1	0.2	0.3	0.6			
Paraffin wax fume	8002–74–2		2					
Paraquat, respirable dust	4685–14–7		0.1					X
Parathion	56–38–2		0.1					X
Particulates not otherwise regulated	N/A.							
	Total dust		15					
	Respirable fraction		5					
Pentaborane	19624–22–7	0.005	0.01	0.015	0.03			
Pentachloro-naphthalene	1321–64–8		0.5					X
Pentachloro-phenol	87–86–5		0.5					X
Pentaerythritol	115–77–5.							
	Total dust		10					
	Respirable fraction		5					
Pentane	109–66–0	600	1800	750	2250			
2-Pentanone (Methyl propyl ketone)	107–87–9	200	700	250	875			
Perchloro-ethylene (Tetrachloro-ethylene)	127–18–4	25	170					
Perchloromethyl mercaptan	594–42–3	0.1	0.8					
Perchloryl fluoride	7616–94–6	3	14	6	28			
Perlite.								
	Total dust		15					
	Respirable fraction		5					
Petroleum distillates (Naphtha)	8002–05–9	400	1600					
Phenol	108–95–2	5	19					X
Phenothiazine	92–84–2		5					X
p-Phenylene diamine	106–50–3		0.1					X
Phenyl ether, vapor	101–84–8	1	7					
Phenyl ether-biphenyl mixture, vapor	N/A	1	7					
Phenylethylene; see Styrene	100–42–5.							
Phenyl glycidyl ether (PGE)	122–60–1	1	6					
Phenylhydrazine	100–63–0	5	20	10	45			X
Phenyl mercaptan	108–98–5	0.5	2					
Phenylphosphine	638–21–1					0.05	0.25	
Phorate	298–02–2		0.05		0.2			X
Phosdrin (Mevinphos®)	7786–34–7	0.01	0.1	0.03	0.3			X
Phosgene (Carbonyl chloride)	75–44–5	0.1	0.4					
Phosphine	7803–51–2	0.3	0.4	1	1			
Phosphoric acid	7664–38–2		1		3			
Phosphorus (yellow)	7723–14–0		0.1					
Phosphorus oxychloride	10025–87–3	0.1	0.6					
Phosphorus pentachloride	10026–13–8		1					
Phosphorus pentasulfide	1314–80–3		1		3			
Phosphorus trichloride	7719–12–2	0.2	1.5	0.5	3			
Phthalic anhydride	85–44–9	1	6					
m-Phthalodinitrile	626–17–5		5					
Picloram	1918–02–1.							
	Total dust		10					
	Respirable fraction		5					
Picric acid	88–89–1		0.1					X
Piperazine dihydrochloride	142–64–3		5					
Pindone (2-Pivalyl- 1,3-indandione)	83–26–1		0.1					
Plaster of Paris	7778–18–9.							
	Total dust		15					
	Respirable fraction		5					
Platinum (as Pt)	7440–06–4.							
	Metal		1					
	Soluble salts		0.002					
Portland cement	65997–15–1.							
	Total dust		10					
	Respirable fraction		5					
Potassium hydroxide	1310–58–3						2	
Propane	74–98–6	1000	1800					
Propargyl alcohol	107–19–7	1	2					X
beta-Propriolactone; see 1910.1013	57–57–8.							
Propionic acid	79–09–4	10	30					
Propoxur (Baygon)	114–26–1		0.5					
n-Propyl acetate	109–60–4	200	840	250	1050			
n-Propyl alcohol	71–23–8	200	500	250	625			
n-Propyl nitrate	627–13–4	25	105	40	170			
Propylene dichloride	78–87–5	75	350	110	510			
Propylene glycol dinitrate	6423–43–4	0.05	0.3					
Propylene glycol monomethyl ether	107–98–2	100	360	150	540			

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Propylene imine	75–55–8	2	5					X
Propylene oxide	75–56–9	20	50					
Propyne; see Methyl acetylene	74–99–7.							
Pyrethrum	8003–34–7		5					
Pyridine	110–86–1	5	15					
Quinone	106–51–4	0.1	0.4					
Resorcinol	108–46–3	10	45	20	90			
Rhodium (as Rh), metal fume and insoluble compounds	7440–16–6		0.1					
Rhodium (as Rh), soluble compounds	7440–16–6		0.001					
Ronnel	299–84–3		10					
Rosin core solder pyrolysis products, as formaldehyde			0.1					
Rotenone	83–79–4		5					
Rouge.								
	Total dust		10					
	Respirable fraction		5					
Selenium compounds (as Se)	7782–49–2		0.2					
Selenium hexafluoride (as Se)	7783–79–1	0.05	0.4					
Silica, amorphous, precipitated and gel			6					
Silica, amorphous, diatomaceous earth, containing less than 1% crystalline silica.	68855–54–9		6					
Silica, crystalline cristobalite respirable dust	14464–46–1		0.05					
Silica, crystalline, quartz, respirable dust	14808–60–7		0.1					
Silica, crystalline tripoli (as quartz), respirable dust	1317–95–9		0.1					
Silica, crystalline tridymite respirable dust	15468–32–3		0.05					
Silica, fused, respirable dust	60676–86–0		0.1					
Silicates (less than 1% crystalline silica)								
Mica (respirable dust)	12001–26–2		3					
Soapstone, total dust			6					
Soapstone, respirable dust			3					
Talc (containing asbestos): Use asbestos limit; see 1910.1001.								
Talc (containing no asbestos), respirable dust	14807–96–6		2					
Tremolite; asbestiform—see 1910.1001; non-asbestiform—see 57 FR 24310, June 8, 1992.								
Silicon	7440–21–3.							
	Total dust		10					
	Respirable fraction		5					
Silicon carbide	409–21–2.							
	Total dust		10					
	Respirable fraction		5					
Silicon tetrahydride	7803–62–5	5	7					
Silver, metal and soluble compounds (as Ag)	7440–22–4		0.01					
Soapstone; see Silicates								
Sodium azide	26628–22–8.							
	(as HN3)					0.1		X
	(as NaN3)						0.3	X
Sodium bisulfite	7631–90–5		5					
Sodium fluoroacetate	62–74–8		0.05		0.15			X
Sodium hydroxide	1310–73–2						2	
Sodium metabisulfite	7681–57–4		5					
Starch	9005–25–8.							
	Total dust		15					
	Respirable fraction		5					
Stibine	7803–52–3	0.1	0.5					
Stoddard solvent	8052–41–3	100	525					
Strychnine	57–24–9		0.15					
Styrene	100–42–5	50	215	100	425			
Subtilisins (Proteolytic enzymes)	1395–21–7						0. 00006	
Sucrose	57–50–1.							
	Total dust		15					
	Respirable fraction		5					
Sulfur dioxide	7446–09–5	2	5	5	13			
Sulfur hexafluoride	2551–62–4	1000	6000					
Sulfuric acid	7664–93–9		1					
Sulfur monochloride	10025–67–9					1	6	
Sulfur pentafluoride	5714–22–7					0.01	0.1	
Sulfur tetrafluoride	7783–60–0					0.1	0.4	
Sulfuryl fluoride	2699–79–8	5	20	10	40			
Sulprofos	35400–43–2		1					
Systox®; see Demeton	8065–48–3.							
2,4,5–T	93–76–5		10					
Talc; see Silicates.								
Tantalum, metal and oxide dust	7440–25–7		5					
TEDP (Sulfotep)	3689–24–5		0.2					X
Tellurium and compounds (as Te)	13494–80–9		0.1					
Tellurium hexafluoride (as Te)	7783–80–4	0.02	0.2					

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
Temephos	3383–96–8.							
	Total dust		10					
	Respirable fraction		5					
TEPP	107–49–3		0.05					X
Terphenyls	26140–60–3					0.5	5	
1,1,1,2-Tetrachloro-2,2-difluoroethane	76–11–9	500	4170					
1,1,2,2-Tetrachloro 1,2-difluoroethane	76–12–0	500	4170					
1,1,2,2-Tetrachloro-ethane	79–34–5	1	7					X
Tetrachoro-ethylene; see Perchloro-ethylene	127–18–4.							
Tetrachloro-methane; see Carbon tetrachloride	56–23–5.							
Tetrachloro-naphthalene	1335–88–2		2					X
Tetraethyl lead (as Pb)	78–00–2		0.075					X
Tetrahydrofuran	109–99–9	200	590	250	735			
Tetramethyl lead (as Pb)	75–74–1		0.075					X
Tetramethyl succinonitrile	3333–52–6	0.5	3					X
Tetranitro-methane	509–14–8	1	8					
Tetrasodium pyrophosphate	7722–88–5		5					
Tetryl (2,4,6-Trinitro-phenyl-methyl-nitramine)	479–45–8		0.1					X
Thallium, soluble compounds (as Tl)	7440–28–0		0.1					X
4,4′-Thiobis (6-tert-Butyl-m-cresol)	96–69–5.							
	Total dust		10					
	Respirable fraction		5					
Thioglycolic acid	68–11–1	1	4					X
Thionyl chloride	7719–09–7					1	5	
Thiram	137–26–8		5					
Tin, inorganic compounds (except oxides) (as Sn)	7440–31–5		2					
Tin, organic compounds (as Sn)	7440–31–5		0.1					X
Tin oxide (as Sn)	7440–31–5		2					
Titanium dioxide	13463–67–7.							
	Total dust		10					
	Respirable fraction		5					
Toluene	108–88–3	100	375	150	560			
Toluene-2,4-diisocyanate (TDI)	584–84–9	0.005	0.04	0.02	0.15			
m-Toluidine	108–44–1	2	9					X
o-Toluidine	95–53–4	5	22					X
p-Toluidine	106–49–0	2	9					X
Toxaphene; see Chlorinated camphene	8001–35–2.							
Tremolite; see Silicates	N/A.							
Tributyl phosphate	126–73–8	0.2	2.5					
Trichloroacetic acid	76–03–9	1	7					
1,2,4-Trichloro-benzene	120–82–1					5	40	
1,1,1-Trichloroethane; see Methyl chloroform	71–55–6.							
1,1,2-Trichloroethane	79–00–5	10	45					X
Trichloro-ethylene	79–01–6	50	270	200	1080			
Trichloro-methane; see Chloroform	67–66–3.							
Trichloro-naphthalene	1321–65–9		5					X
1,2,3-Trichloropropane	96–18–4	10	60					
1,1,2-Trichloro-1,2,2-trifluoroethane	76–13–1	1000	7600	1250	9500			
Triethylamine	121–44–8	10	40	15	60			
Trifluorobromo-methane	75–63–8	1000	6100					
Trimellitic anhydride	552–30–7	0.005	0.04					
Trimethylamine	75–50–3	10	24	15	36			
Trimethyl benzene	25551–13–7	25	125					
Trimethyl phosphite	121–45–9	2	10					
2,4,6-Trinitrophenyl; see Picric acid	88–89–1.							
2,4,6-Trinitrophenylmethyl nitramine; see Tetryl	479–45–8.							
2,4,6-Trinitrotoluene (TNT)	118–96–1		0.5					X
Triorthocresyl phosphate	78–30–8		0.1					X
Triphenyl amine	603–34–9		5					
Triphenyl phosphate	115–86–6		3					
Tungsten (as W)	7440–33–7.							
	Insoluble compounds.		5		10			
	Soluble compounds.		1		3			
Turpentine	8006–64–2	100	560					
Uranium (as U)	7440–61–1.							
	Soluble compounds.		0.05					
	Insoluble compounds.		0.2		0.6			
n-Valeraldehyde	110–62–3	50	175					
Vanadium	1314–62–1.							
	Respirable Dust as V205.		0.05					
	Fume (as V205)		0.05					
Vegetable Oil Mist	N/A.							
	Total dust		15					

TABLE Z–1–A—LIMITS FOR AIR CONTAMINANTS—Continued

[From the vacated 1989 final rule—*Ex. #149*]

Substance	Cas No.	TWA		STEL		Ceiling		Skin Designation
		ppm	mg/m³	ppm	mg/m³	ppm	mg/m³	
	Respirable fraction		5					
Vinyl acetate	108–05–4	10	30	20	60			
Vinyl benzene; see Styrene	100–42–5.							
Vinyl bromide	593–60–2	5	20					
Vinyl chloride; see 1910.1017	75–01–4.							
Vinyl cyanide; see Acrylonitrile	107–13–1.							
Vinyl cyclohexene dioxide	106–87–6	10	60					X
Vinylidene chloride (1,1-Dichloro-ethylene)	75–35–4	1	4					
Vinyl toluene	25013–15–4	100	480					
VM & P Naphtha	8032–32–4	300	1350	400	1800			
Warfarin	81–81–2		0.1					
Welding fumes (total particulate)*	N/A		5					
Wood dust, all soft and hard woods, except Western red cedar.	N/A		5		10			
Wood dust, western red cedar	N/A		2.5					
Xylenes (o-, m-, p-isomers)	1330–20–7	100	435	150	655			
m-Xylene alpha, alpha' diamine	1477–55–0						0.1	X
Xylidine	1300–73–8	2	10					X
Yttrium	7440–65–5		1					
Zinc chloride fume	7646–85–7		1		2			
Zinc chromate (as CrO3); see 910.1026. See Table Z–2 for the exposure limit for any operations or sectors where the exposure limit in 1910.1026 is stayed or are otherwise not in effect.	Varies with compound.							
Zinc oxide fume	1314–13–2		5		10			
Zinc oxide	1314–13–2.							
	Total dust		10					
	Respirable fraction		5					
Zinc stearate	557–05–1.							
	Total dust		10					
	Respirable fraction		5					
Zirconium compounds (as Zr)	7440–67–7		5		10			

[1](30 minutes).

References by Exhibit Number

Ex. #1: U.S. Environmental Protection Agency. (2013a). 2012 Chemical Data Reporting Results. Retrieved from: *http://epa.gov/cdr/pubs/guidance/cdr_factsheets.html.*

Ex. #2: Hogue, C. (2007). Point/Counterpoint: The Future of U.S. Chemical Regulation. *Chemical and Engineering News,* 85(2), 34–38.

Ex. #3: European Chemicals Agency. (2013). Registered Substances. Retrieved from: *http://echa.europa.eu/information-on-chemicals/registered-substances.*

Ex. #4: Air Contaminants, Tables Z–1, Z–2, and Z–3, 29 CFR 1910.1000 (2012).

Ex. #5: Air Contaminants, 29 CFR 1915.1000 (2012).

Ex. #6: Gases, vapors, fumes, dusts, and mists, 29 CFR 1926.55 (2012).

Ex. #7: Air Contaminants, 54 FR 2332 (Jan. 19, 1989).

Ex. #8: AFL–CIO v. *OSHA,* 965 F.2d 962 (11th Cir. 1992) (''*Air Contaminants*'').

Ex. #9: Occupational Safety and Health Act of 1970, 29 U.S.C. 651, 652(8), 655(a), 655(b)(5), 655(f) (2006).

Ex. #10: Industrial Union Dept., AFL–CIO v. *American Petroleum Institute,* 448 U.S. 607 (1980) (''*Benzene*'').

Ex. #11: Occupational Exposure to Formaldehyde Final Rule, 52 FR 46168 (December 4, 1987).

Ex. #12: United Steelworkers v. *Marshall,* 647 F.2d 1189 at 1264 (D.C. Cir. 1980) (''*Lead I*'').

Ex. #13: Color Pigments Manufacturers Assoc. v. *OSHA,* 16 F.3d 1157, 1162–63 (11th Cir. 1994).

Ex. #14: Public Citizen Health Research Group v. *United States Department of Labor,* 557 F.3d 165 (3d Cir. 2009).

Ex. #15: American Textile v. *Donovan,* 452 U.S. 490 (1981) (''*Cotton Dust*'').

Ex. #16: Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951).

Ex. #17: Senate Report (Labor and Pubic Welfare Committee) S. REP. 91–1282 (1970).

Ex. #18: Air Contaminants Proposed Rule, 53 FR 20960 (Jun. 7, 1988).

Ex. #19: Air Contaminants Final Rule, 58 FR 35338 (Jun. 30, 1993).

Ex. #20: Unified Agenda, The Regulatory Plan, DOL–OSHA, Permissible Exposure Limits (PELS) for Air Contaminants, 60 FR 59628 (Nov. 28, 1995).

Ex. #21: Notice of Public Meeting on Updating Permissible Exposure Limits (PELs) for Air Contaminants, 61 FR 1947 (Jan. 24, 1996).

Ex. #22: Unified Agenda, The Regulatory Plan, DOL–OSHA, Permissible Exposure Limits (PELS) for Air Contaminants, 66 FR 61882 (Dec. 3, 2001).

Ex. #23: National Research Council. (2012). Exposure science in the 21st century: a vision and a strategy. Retrieved from: *http://nap.edu/catalog.php?record_id=13507.*

Ex. #24: National Research Council. (2009). Science and decisions: advancing risk assessment. Retrieved from: *http://www.nap.edu/catalog.php?record_id=12209.*

Ex. #25: National Research Council. (2007). Toxicity testing in the 21st century: a vision and a strategy. Retrieved from: *http://www.nap.edu/catalog.php?record_id=11970.*

Ex. #26: Occupational Exposure to Hexavalent Chromium, 71 FR 10099 (Feb. 28, 2006).

Ex. #27: Occupational Exposure to Methylene Chloride, 62 FR 1494 (Jan. 10, 1997).

Ex. #28: National Research Council. (1983). Risk assessment in the federal government: managing the process. Retrieved from: *http://www.nap.edu/openbook.php?isbn=0309033497.*

Ex. #29: Hill, A.B. (1965). The environment and disease: association or causation? *Proceedings of the Royal Society of Medicine, 58(5),* 295–300.

Ex. #30: Rothman, K.J., Greenland, S. *Modern Epidemiology.* Philadelphia, Pa.: Lippincott, 1998.

Ex. #31: Environmental Protection Agency—Integrated Risk Information System (1994) Methods for derivation of inhalation reference concentrations and applications of inhalation dosimetry. Washington, DC (EPA/600/8–90/066f).

Ex. #32: U.S. Environmental Protection Agency. (2005). Guidelines for carcinogen risk assessment (EPA/630/P–03/001F).

Ex. #33: European Chemicals Bureau (ECB). (2003). Technical guidance on risk assessment. Retrieved from: *http://publications.jrc.ec.europa.eu/repository/handle/111111111/5619?mode=full.*

Ex. #34: Presidential/Congressional Commission on Risk Assessment and Risk Management (PCRARM). (1997). Risk assessment and risk management in regulatory decision-making. Retrieved from: *http://cfpub.epa.gov/ncea/cfm/pcrarm.cfm.*

Ex. #35: U.S. Environmental Protection Agency. (2002). A review of the reference dose and reference concentration processes (EPA/630/P–02–002F).

Ex. #36: International Programme on Chemical Safety (IPCS). (2005). Chemical-specific adjustment factors for interspecies differences and human variability: guidance document for use of data in dose/concentration-response assessment. Retrieved from: *http://www.inchem.org/documents/harmproj/harmproj/harmproj2.pdf.*

Ex. #37: European Chemicals Agency (ECHA). (2012a). Guidance on information requirements and chemical safety assessment, chapter R.8: characterization of dose [concentration]-response for human health. Retrieved from: *http://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf.*

Ex. #38: U.S. Environmental Protection Agency. (2011). Guidance for applying quantitative data to develop data-derived extrapolation factors for interspecies and intraspecies extrapolation (EPA/100/J–11/001). Retrieved from: *http://www.epa.gov/raf/files/ddef-external-review-draft 05-11-11.pdf.*

Ex. #39: Organization for Economic Co-operation and Development (OECD). (2007). Guidance on grouping of chemicals. (ENV/JM/MONO (2007) 28). Retrieved from: *http://search.oecd.org/officialdocuments/displaydocumentpdf/?doclanguage=en&cote=env/jm/mono%282007%2928.*

Ex. #40: National Toxicology Program (NTP). (2013). High Throughput Screening Initiative. Retrieved from: *http://ntp.niehs.nih.gov/go/28213.*

Ex. #41: U.S. Environmental Protection Agency. (2013b). NexGen: Advancing the Next Generation of Risk Assessment. Retrieved from: *http://www.epa.gov/risk/nexgen.*

Ex. #42: Patankar, S.V., Numerical Heat Transfer and Fluid Flow. New York: McGraw-Hill, 1980.

Ex. #43: National Institute for Occupational Safety and Health. (2011a). Experimental and Numerical Research on the Performance of Exposure Control Measures for Aircraft Painting Operations, Part I (EPHB Report No. 329–12a).

Ex. #44: National Institute for Occupational Safety and Health. (2010). Workplace Safety & Health Topics: Aerosols. Retrieved from: *http://www.cdc.gov/niosh/topics/aerosols/internal_research.html.*

Ex. #45: National Institute for Occupational Safety and Health. (2011b). NORA Manufacturing Sector Strategic Goals. Retrieved from: *http://www.cdc.gov/niosh/programs/manuf/noragoals/projects/921Z6KR.html.*

Ex. #46: Yuan, L., Smith, A.C., and Brune, J.F. (2006). Computational Fluid Dynamics Study on the Ventilation Flow Paths in Longwall Gobs. *Proceedings of the 11th U.S./North American Mine Ventilation Symposium,* University Park, Pennsylvania.

Ex. #47: Edwards, J.C. and Hwang, C.C. (2006). CFD Modeling of Fire Spread Along Combustibles in a Mine Entry. Retrieved from: *http://www.cdc.gov/niosh/mining/UserFiles/works/pdfs/cmofs.pdf.*

Ex. #48: Trevits, M.A., Yuan, L., Thibou, M., Hatch, G. (2010). Use of CFD Modeling to Study Inert Gas Injection into a Sealed Mine Area. SME Annual Meeting, Phoenix, Arizona.

Ex. #49: U.S. Environmental Protection Agency and U.S. Department of Energy. (2008). Laboratories for the 21st Century: Best Practice Guide.

Ex. #50: National Institute of Standards and Technology (NIST). (1997). Use of Computational Fluid Dynamics to Analyze Indoor Air Quality Issues (NISTIR 5997).

Ex. #51: National Institute of Standards and Technology (NIST). (2009). NIST Technical Note 1637: Modeling the Effects of Outdoor Gasoline Powered Generator Use on Indoor Carbon Monoxide Exposures.

Ex. #53: American Dental Ass'n v. *Martin,* 984 F.2d 823 (7th Cir. 1993).

Ex. #54: Assoc. Bldrs & Contrs. Inc. v. *Brock,* 862 F.2d 63 (3d Cir. 1988).

Ex. #55: Industrial Union Dep't, AFL–CIO v. *Hodgson,* 499 F.2d 467 (D.C. Cir. 1974).

Ex. #56: U.S. Environmental Protection Agency. (2012a). High Production Volume Information System (HPVIS). Retrieved from: *http://www.epa.gov/chemrtk/hpvis/index.html.*

Ex. #57: U.S. Environmental Protection Agency. (2013c). TSCA Interagency Testing Committee (ITC). Retrieved from: *http://www.epa.gov/oppt/itc/index.htm.*

Ex. #58: Organization for Economic Cooperation and Development (OECD). (2013). eChemPortal. Retrieved from: *http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en.*

Ex. #59: U.S. Environmental Protection Agency. (2014a). Computational Toxicology Research. Retrieved from: *http://www.epa.gov/ncct/toxcast/.*

Ex. #60: U.S. Environmental Protection Agency. (2014). ToxCast™ Advancing the next generation of chemical safety evaluation. Retrieved from: *http://www.epa.gov/ncct/.*

Ex. #61: REACH Fact Sheet: Safety Data Sheets and Exposure Scenarios. European Chemicals Agency (ECHA). (2011). REACH Fact Sheet: Safety Data Sheets and Exposure Scenarios. ECHA–11–FS–02.1–EN.

Ex. #62: Toxic Substances Control Act, 15 U.S.C. 2601–2629 (2011).

Ex. #63: U.S. Environmental Protection Agency. (2013d). HPV Chemical Hazard Characterizations. Retrieved from: *http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=2.*

Ex. #64: Russom, C.L., Breton, R.L., Walker, J.D., & Bradbury, S.P. (2003). An overview of the use of quantitative structure-activity relationships for ranking and prioritizing large chemical inventories for environmental risk assessments. *Environmental Toxicology and Chemistry, 22*(8), 1810–1821.

Ex. #65: U.S. Government Accountability Office (GAO). (2007). Chemical regulation: comparison of U.S. and recently enacted European Union approaches to protect against the risks of toxic chemicals (GAO–07–825).

Ex. #66: Zeeman, M. (1995). EPA's framework for ecological effects assessment. In Office of Technology Assessment, Screening and Testing Chemicals in Commerce (pp. 169–178) (OTA–BP–ENV–166).

Ex. #67: U.S. Environmental Protection Agency. (2012b). Ecological Structure Activity Relationships (ECOSAR). Retrieved from: *http://www.epa.gov/oppt/newchems/tools/21ecosar.htm.*

Ex. #68: European Chemicals Agency (ECHA). Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARS and grouping of chemicals. May 2008

Ex. #69: OSPAR Commission. (2000). Briefing document of the work of DYNAMEC and the DYNAMEC Mechanism for the selection and prioritization of hazardous substances. Retrieved from: *http://www.ospar.org/documents/dbase/publications/p00104/p00104_briefing%20doc%20on%20dynamec.pdf.*

Ex. #70: Regulation of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), EC No. 1907/2006 (2006).

Ex. #71: European Chemicals Agency (ECHA). (2012b). Information Requirements. Retrieved from: *http://echa.europa.eu/web/guest/regulations/reach/substance-registration/information-requirements.*

Ex. #72: European Chemicals Agency (ECHA). (2012c). Information on Chemicals. Retrieved from: *http://echa.europa.eu/web/guest/information-on-chemicals.*

Ex. #73: European Chemicals Agency (ECHA). (2009). *Guidance in a nutshell: Chemical Safety Assessment.*

Ex. #74: European Chemicals Agency (ECHA). (2012d). Evaluation. Retrieved from: *http://echa.europa.eu/regulations/reach/evaluation.*

Ex. #75: Kriebel, D., Jacobs, M. M., Markkanen, P., & Tickner, J. (2011). Lessons learned: Solutions for workplace safety and health. Lowell, MA: Lowell Center for Sustainable Production. Retrieved from: *http://www.sustainableproduction.org/downloads/LessonsLearned-FullReport.pdf.*

Ex. #76: Wilson, M.P., Hammond, S.K., Nicas, M., & Hubbard, A.E. (2007). Worker exposure to volatile organic compounds in the vehicle repair

industry. *Journal of Occupational and Environmental Hygiene, 4, 301–310.*

Ex. #77: Massachusetts Department of Environmental Protection. (n.d.). Toxics Use Reduction Act. Retrieved from: *http://www.mass.gov/dep/toxics/toxicsus.htm.*

Ex. #78: Toxics Use Reduction Institute. (2011a). About TUR plans and planning. Retrieved from: *http://www.turi.org/Our_Work/Training/TUR_Planner_Program/About_TUR_Plans_and_Planning.*

Ex. #79: Toxics Use Reduction Institute. (2011b). Trichloroethylene and chlorinated solvents reduction. Retrieved from: *http://www.turi.org/Our_Work/Green_Cleaning_Lab/How_We_Can_Help/Cleaning_Research_Projects/Trichloroethylene-and-Chlorinated-Solvents-Reduction.*

Ex. #80: Toxics Use Reduction Institute. (2011c). CleanerSolutions database. Retrieved from: *http://www.turi.org/Our_Work/Green_Cleaning_Lab/Does_It_Clean/CleanerSolutions_Database.*

Ex. #81: Toxics Use Reduction Institute. (2011d). TCE facts: Use nationally and in Massachusetts. Retrieved from: *http://www.turi.org/About/Library/TURI-Publications/Massachusetts_Chemical_Fact_Sheets/Trichloroethylene_TCE_Fact_Sheet/TCE_Facts/Use_Nationally_and_in_Massachusetts.*

Ex. #82: Roelofs, C.R., Barbeau, E.M., Ellenbecker, M.J., & Moure-Eraso, R. (2003). Prevention strategies in industrial hygiene: A critical literature review. *AIHA Journal, 64*(1), 62–67.

Ex. #83: American Industrial Hygiene Association. (2008). Demonstrating the business value of industrial hygiene: Methods and findings from the value of the industrial hygiene profession study. Retrieved from: *http://www.aiha.org/votp_new/pdf/votp_report.pdf.*

Ex. #84: Lavoie, E.T., Heine, L.G., Holder, H., Rossi, M.S., Lee II, R.E., Connor, E.A., . . . Davies, C.L. (2010). Chemical alternatives assessment: Enabling substitution to safer chemicals. *Environmental Science & Technology, 44*(24), 9244–9249.

Ex. #85: Toxics Use Reduction Institute. (2006). Five chemicals alternatives assessment study. Retrieved from: *http://www.turi.org/About/Library/TURI-Publications/2006_Five_Chemicals_Alternatives_Assessment_Study.*

Ex. #86: Rossi, M., Tickner, J., & Geiser, K. (2006). Alternatives assessment framework of the Lowell Center for Sustainable Production. Lowell, MA: Lowell Center for Sustainable Production. Retrieved from: *http://www.chemicalspolicy.org/downloads/FinalAltsAssess06.pdf.*

Ex. #87: Raphael, D.O. & Geiger, C.A. (2011). Precautionary policies in local government: Green chemistry and safer alternatives. *New Solutions, 21*(3), 345–358.

Ex. #88: Clean Production Action. (2012). GreenScreen for Safer Chemicals v1.2. Retrieved from: *http://www.cleanproduction.org/Greenscreen.v1-2.php.*

Ex. #89: U.S. Environmental Protection Agency. (2011a). DfE's standard and criteria for safer chemical ingredients. Retrieved from: *http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#.*

Ex. #90: Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA). (2011). The GHS Column Model: An aid to substitute assessment. Berlin, Germany: Deutsche Gesetzliche Unfallversicheung e.V. (DGUV).

Ex. #91: Netherlands Ministry of Infrastructure and the Environment. (2002). Implementation strategy on management of substances: 2nd progress report. Retrieved from: *http://www.subsport.eu/images/stories/pdf_archive/substitution_tools/15_quick_scan_en.pdf.*

Ex. #92: Identification, Classification, and Regulation of Potential Occupational Carcinogens, 45 FR 5258 (Jan. 22, 1980).

Ex. #93: OSHA Cancer Policy, 29 CFR 1990.111(k) (2011).

Ex. #94: OSHA Cancer Policy, 29 CFR 1990.132(b)(6) (2011).

Ex. #95: OSHA Cancer Policy, 29 CFR 1990.146(k) (2011).

Ex. #96: Respiratory Protection, 29 CFR 1910.134(a) (2011).

Ex. #97: Air Contaminants, 29 CFR 1910.1000(e) (2011).

Ex. #98: Occupational Exposure to Methylene Chloride, 62 FR 1494 (Jan. 10, 1997).

Ex. #99: Occupational Exposure to Hexavalent Chromium, 71 FR 10099 (Feb. 28, 2006).

Ex. #100: Occupational Safety and Health Administration. (1996). Final economic and regulatory flexibility analysis for OSHA's standard for occupational exposure to methylene chloride.

Ex. #101: Occupational Safety and Health Administration. (2006a). Final economic and regulatory flexibility analysis for OSHA's final standard for occupational exposure to hexavalent chromium.

Ex. #102: Occupational Safety and Health Administration. (1987). Regulatory impact and regulatory flexibility analysis of the formaldehyde standard.

Ex. #103: Occupational Safety and Health Administration. (1984). Regulatory impact and regulatory flexibility analysis of the final standard for ethylene oxide.

Ex. #104: Occupational Safety and Health Administration. (2005). Regulatory Review of the Occupational Safety and Health Administration's Ethylene Oxide Standard [29 CFR 1910.1047].

Ex. #105: Occupational Safety and Health Administration. (2010). Regulatory Review of 29 CFR 1910.1052: Methylene chloride.

Ex. #106: Occupational Safety and Health Administration. (2006b). Best practices for the safe use of glutaraldehyde in health care (OSHA 3254–08N 2006).

Ex. #107: Occupational Safety and Health Administration. (2013a). Transitioning to safer chemicals: a toolkit for employers and workers. Retrieved from: *http://www.osha.gov/dsg/safer_chemicals/.*

Ex. #108: American National Standard for Occupational Health and Safety Management Systems, ANSI/AIHA Z10–2005 (2005).

Ex. #109: Council Directive on the Protection of the Health and Safety of Workers from the Risks Related to Chemical Agents at Work, 98/24/EC (1998).

Ex. #110: Directive of the European Parliament and of the Council on the Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work, 2004/37/EC (2004).

Ex. #111: Safe Alternatives Policy, 42 U.S.C. 7671K (2011).

Ex. #113: European Commission. (2012). Minimising chemical risk to workers' health and safety through substitution. Retrieved from: *https://osha.europa.eu/en/news/eu-minimising-chemical-risk-to-workers-health-and-safety-through-substitution.*

Ex. #114: German Federal Institute for Occupational Safety and Health (BAuA), Hazardous Substances Ordinance (Gefahrstoffverordnung—GefStoffV) (July 28, 2011).

Ex. #115: German Federal Institute for Occupational Safety and Health (BAuA), Technical Rule on Hazardous Substances (TRGS) 600 (Aug. 2008).

Ex. #116: German Environment Agency (Umweltbundesamt). (2011). Guide on sustainable chemicals: A decision tool for substance manufacturers, formulators, and end users of chemicals. Retrieved from: *http://www.umweltdaten.de/publikationen/fpdf-l/4169.pdf.*

Ex. #117: GreenBlue. (2012). CleanGredients. Retrieved from: *http://www.cleangredients.org/home.*

Ex. #118: Institute of Work, Environment, and Health (ISTAS). (2012). RISCTOX. Retrieved from: *http://www.istas.net/risctox/en/.*

Ex. #119: SUBSPORT. (2012). Substitution Support Portal. Retrieved from: *http://www.subsport.eu/about-the-project.*

Ex. #120: U.S. Environmental Protection Agency. (2012c). Alternatives assessments. Retrieved from: *http://www.epa.gov/dfe/alternative_assessments.html.*

Ex. #121: U.S. Environmental Protection Agency. (2011b). The U.S. Environmental Protection Agency's strategic plan for evaluating the toxicity of chemicals. Retrieved from: *http://www.epa.gov/spc/toxicitytesting/.*

Ex. #122: U.S. Environmental Protection Agency. (2012d). Overview of National Research Council toxicity testing strategy. Retrieved from: *http://www.epa.gov/pesticides/science/nrc-toxtesting.html.*

Ex. #123: Washington Department of Ecology. (2012). Ecology Quick Chemical Assessment Tool 1.2 Methodology. Retrieved from: *http://www.ecy.wa.gov/programs/hwtr/ChemAlternatives/documents/QCAT2012-03-20final.pdf.*

Ex. #124: Hazard Communication, 29 CFR 1910.1200 (2012).

Ex. #125: Hazard Communication, 77 FR 17574 (Mar. 26, 2012).

Ex. #126: National Safety Council, Fundamentals of Industrial Hygiene

(2012) ed. Plog, B.A. and Quinlan, P. J. Chapter 31, International Developments in Occupational Safety and Health, Silk, J. and Brigandi, P.

Ex. #127: Taylor-McKernan, L. and Seaton M. (2014) The Banding Marches On, NIOSH Proposes a New Process for Occupational Exposure Banding. The Synergist, May, p. 44–46.

Ex. #128: Laszcz-Davis, C., Maier, A., Perkins, J. (2014) The Hierarchy of OELs, A New Organizing Principle for Occupational Risk Assessment, The Synergist, March, p. 27–30.

Ex. #129: Health and Safety Executive. (2013). COSHH Essentials. Retrieved from: *http://www.hse.gov.uk/coshh/essentials/.*

Ex. #130: Control of Substances Hazardous to Health Regulations, 2002 No. 2677 (2002).

Ex. #131: Health and Safety Executive. (2009). The technical basis for COSHH essentials: easy steps to control chemicals. Retrieved from: *http://coshh-essentials.org.uk/assets/live/CETB.pdf.*

Ex. #132: Jones, R.M., Nicas, M., (2006) Evaluation of COSHH Essentials for vapor degreasing and bag filling operations. *Annals of Occupational Hygiene, 50*(2), 137–147.

Ex. #133: Hashimoto, H., Toshiaki, G., Nakachi, N., Suzuki, H., Takebayashi, T., Kajiki, S., Mori, K. (2007) Evaluation of the Control Banding Method—Comparison with Measurement-based Comprehensive Risk Assessment. *Journal of Occupational Health, 49,* 482–492.

Ex. #134: Lee, E.G., Slaven, J., Bowen, R.B., Harper, M. (2011). Evaluation of the COSHH Essentials Model with a Mixture of Organic Chemicals at a Medium-Sized Paint Producer. *Annals of Occupational Hygiene, 55*(1), 16–29.

Ex. #135: National Institute for Occupational Safety and Health (NIOSH). (2009). Qualitative risk characterization and management of occupational hazards: control banding (CB), a literature review and critical analysis (DHHS (NIOSH) Publication No. 2009–152).

Ex. #136: Occupational Safety and Health Administration. (2009). Controlling silica exposures in construction (OSHA 3362–05 2009).

Ex. #137: Occupational Safety and Health Administration. (2013b). Notice of proposed rulemaking for occupational exposure to respirable crystalline silica.

Ex. 138: Susi, et. al. (2000). The use of a task-based exposure assessment model (T–BEAM) for assessment of metal fume exposures during welding and thermal cutting. Applied Occupational and Environmental Hygiene, 15(1): 26–38.

Ex. #139: Burg, F. (2012). Standards insider. Professional Safety, 57(3), 24–25.

Ex. #140: Marine Terminals, 29 CFR 1917.2, 1917.22, 1917.23, 1917.25 (2012).

Ex. #141: Safety and Health Regulations for Longshoring. 29 CFR 1918 (2012).

Ex. #142: National Consensus Standards and Established Federal Standards, 36 FR 10466 (May 29, 1971).

Ex. #143: Longshore and Harbor Workers' Compensation, 33 U.S.C. 901–950 (2006).

Ex. #144: Occupational Safety and Health Standards for Shipyard Employment, 29 CFR 1915.11, 1915.12, 1915.32, 1915.33 (2012).

Ex. #145: Federal Advisory Committee on Occupational Safety and Health (FACOSH). (2012). Recommendations for Consideration by the U.S. Secretary of Labor on the Adoption and Use of Occupational Exposure Limits by Federal Agencies.

Ex. #146: Air Contaminants Proposed Rule, 57 FR 26002 (Jun. 12, 1992).

Ex. #147: American Iron and Steel Institute (AISI). (1990). On Petition for Review of Final Rule of Occupational Safety and Health Administration: Industry Petitioners' Joint Procedural Brief.

Ex. #148: Forging Indus. Ass'n v. *Secretary of Labor,* 773 F.2d 1436, 1453 (4th Cir. 1985).

Ex. #149: 1989 PELs Table. 54 FR 2332, 2923–2959.

[FR Doc. 2014–24009 Filed 10–9–14; 8:45 am]

BILLING CODE 4510–26–P