Qualitative Risk Characterization and Management of Occupational Hazards (Control Banding [CB])

A Literature Review and Critical Analysis

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Disclaimer

Mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH). In addition, citations to Web sites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these Web sites.

Ordering Information

To receive documents or other information about occupational safety and health topics, contact NIOSH at

Telephone: 1–800–CDC–INFO (1–800–232–4636)

TTY: 1–888–232–6348

E-mail: cdcinfo@cdc.gov

or visit the NIOSH Web site at **www.cdc.gov/niosh**.

For a monthly update on news at NIOSH, subscribe to NIOSH *eNews* by visiting **www.cdc.gov/niosh/eNews**.

DHHS (NIOSH) Publication No. 2008–XXX

May 2008

SAFER • HEALTHIER • PEOPLE™

FOREWORD

When the U.S. Congress passed the Occupational Safety and Health Act of 1970 (Public Law 91-596), it established the National Institute for Occupational Safety and Health (NIOSH). Through the Act, Congress charged NIOSH with recommending occupational safety and health standards and describing exposure levels that are safe for various periods of employment, including but not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience. By means of criteria documents, NIOSH communicates these recommended standards to regulatory agencies (including the Occupational Safety and Health Administration [OSHA]), health professionals in academic institutions, industry, organized labor, public interest groups, and others in the occupational safety and health community. Criteria documents contain a critical review of the scientific and technical information about the prevalence of hazards, the existence of safety and health risks, and the adequacy of control methods.

In addition to provision of guidance for specific hazards and workplaces through criteria documents, NIOSH is tasked with assessing and providing technical solutions and promising intervention strategies to protect the safety and health of workers. One such emerging strategy that has gained increasing attention among safety and health practitioners is a qualitative risk characterization and management approach, also referred to as control banding (CB). This document is derived from literature reviews of recent developments describing such exposure characterization and risk management strategies in occupational settings. In particular this document summarizes the literature describing qualitative risk assessment and management strategies, examining situations in which such strategies have been utilized and describing the outcomes of those experiences. The intent of this review is to provide a broad description of qualitative risk management approaches to occupational hazards, recognizing that a deliberate and extensive review of the literature for this topic will help guide decisions for where CB applications may be most effective and where limitations may require additional research or modification, or may preclude their use altogether. In meeting this objective, this document also intends to inform its audience of occupational safety and health practitioners, researchers, policy and decision makers, employers, workers, and others of the concepts of CB and the potential promise it holds as a tool for use within a broader comprehensive occupational safety and health program

John Howard, M.D.
Director, National Institute for
Occupational Safety and Health
Centers for Disease Control and Prevention

EXECUTIVE SUMMARY

The majority of chemical substances in commerce have no established occupational exposure limits (OELs). In the absence of established OELs, employers and workers often lack the necessary guidance on the extent to which occupational exposures should be controlled. An approach to controlling occupational exposures that may have value when there are no relevant OELs is known as control banding (CB). Control banding is a qualitative approach for assessing and managing hazards associated with chemical exposures in the workplace. The question about the utility of the CB approach for workplaces in the United States has been raised, warranting a critical review of its concepts and applications. This report is the result of a review of the published literature and related proceedings on CB.

The conceptual basis for control banding is the grouping of chemical exposures according to similar physical and chemical characteristics, intended processes/handling, and anticipated exposure scenarios (amount of chemical used and how workers would be exposed). Based on these factors, appropriate control strategies (that is, risk management options) are determined for each of these groupings. In one of the least complex forms, a four-level hierarchy of risk management options for controlling exposures to chemicals includes:

1. good occupational hygiene practices, which may be supplemented by use of appropriate personal protective equipment (PPE),
2. engineering controls, including local exhaust ventilation (LEV),
3. containment, and
4. seeking specialist advice.

To determine the appropriate control strategy (CS), consideration is given to the characteristics of a particular chemical substance and the potential for exposure (based on quantity in use, volatility, or dustiness, and the relative hazard as described in what is known as a Risk Phrase, or R-phrase). The latter consideration involves characterization of the process or activity in which the chemical substance is used. These variables help to determine assignment of the chemical substance to a control band. These control bands can be used to provide guidance for various control options and recommendations for PPE based on a qualitative assessment of the chemical exposure.

A variety of CB models were found within the published literature on control banding, each with varying levels of complexity and applicability. The utility of qualitative risk management strategies such as CB has been recognized by a number of international organizations. Widening interest in this approach can be gauged by a growing literature describing elements of qualitative risk management approaches and in some cases, very well-developed models of practice. This report attempts to capture the state-of-the-science of CB as reflected in research and practice. From the published literature and information gleaned from proceedings of recent international workshops, symposia, and conferences on this subject, the following major themes related to the CB have emerged:

- Factors influencing the evolution of qualitative risk characterization and management of occupational hazards
- Models of practice
- Applicability and limitations of practice
- Needs for future research, evaluation, and validation

These themes are based on interpretations of current studies and an understanding of the topic. This literature review can serve as a means to educate employers, workers, safety and health practitioners, and other audiences about the concepts of CB and to stimulate further dialogue about its potential usefulness in the United States by providing the appropriate background information and resources.

The scope of this document includes CB strategies, presented within the context of qualitative occupational risk management concepts. The risk management process associated with CB is characterized by selection and implementation of appropriate control solutions, often in the absence of OELs, to reduce work-related exposures that may lead to occupational disease, illness, and injury. The use of R-phrases or their equivalents in the Global Harmonization System (GHS) in CB is a useful practice, but it is not intended to replace OELs, exposure assessment, or classic IH protocol (i.e., hierarchy of controls) on which CB is based. This review indicates that CB is a potentially valuable tool for risk management of some chemical agents and other occupational hazards; however, continued research and validation efforts are needed. Investigation and application of CB principles to other hazardous agents also appear warranted. If CB is to be useful in the United States, it is recommended that the following actions occur:

1. Increase the awareness and standardization of concepts associated with CB;
2. Ensure validation of qualitative risk assessment and management strategies, tools, and the control-focused solutions;

3. Coordinate efforts for developing, implementing, evaluating, and disseminating qualitative risk assessment and risk management approaches to improve awareness and utility of task specific hazard control guidance;
4. Foster national and international coordination and collaboration in focusing on applications for control-focused solutions for high-risk tasks, industries, and small business enterprises;
5. Consider CB models for broader applications to address additional workplace hazards (e.g., more complex chemical exposures, dermal exposure hazards, ergonomic hazards, and other physical hazards).

Contents not edited till final.

CONTENTS

ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
ACGIH®	American Conference of Governmental Industrial Hygienists
ACoP	Approved Code of Practice
ACS	American Chemical Society
AEGL	EPA Acute Exposure Guidelines Levels (AEGLs) Committee
AIHA	American Industrial Hygienists Association
AIHce	American Industrial Hygiene Conference and Exposition
ANSI	American National Standards Institute
APEC	Asia-Pacific Economic Cooperation
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German BAuA)
BIOH	British Institute of Occupational Hygienists
BOHS	British Occupational Hygiene Society
CAS	Chemical Abstracts Service
CB	control banding
CDC	Centers for Disease Control and Prevention
CEFIC	Conseil Européen de l'Industrie Chimique (European Chemical Industry Council)
CEMAS	CEFIC Exposure Management System
CHIP	Chemical Hazardous Information and Packaging
CGS	control guidance sheets
CIA	Chemicals Industry Association
COSHH	Control of Substances Hazardous to Health
CPSC	Consumer Product Safety Commission
CS	control strategy

dB	decibels
DOT	U.S. Department of Transportation
DPGME	diproplyene glycol monomethyl ether
DREAM	Dermal Exposure Assessment Method
EASE	Estimation and Assessment of Substances Exposure
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EINECS	European Inventory of Existing Commercial chemical Substances
EPA	U.S. Environmental Protection Agency
EPL	exposure predictor bands for liquids
EPS	exposure predictor bands for solids
ES&H	Environmental Safety and Health
EU	European Union
FR	Federal Register
GHS	Globally Harmonized System for Classification and Labeling of chemicals
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HCS	Hazard Communication Standard
HHE	Health Hazard Evaluation
HPV	high production volume
HSDB	Hazardous Substances Data Base
HSE	Health and Safety Executive (of the United Kingdom)
IALI	International Association of Labour Inspectors
ICBW1	First International Control Banding Workshop
ICBW2	Second International Control Banding Workshop
ICCT	International Chemical Control Toolkit
ICOH	International Commission on Occupational Health
ICSC	International Chemical Safety Cards

IEA	International Ergonomics Association
IH	industrial hygiene
ILO	International Labor Office
ILO/OSH	International Labor Office/Occupational Safety and Health
IOHA	International Occupational Hygiene Association
INRS	Institut National de Recherche et de Sécurité
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
ITG	International Technical Group
LEV	local exhaust ventilation
LOAEL	lowest observed adverse effect level
MAK	Maximale Arbeitsplatzkonzentration (maximum concentration of a substance in the ambient air in the workplace)
MEKP	methyl ethyl ketone peroxide
MEL	maximum exposure limit
m^3	cubic meters
mg	milligram(s)
mg/kg/day	milligrams per kilogram of body weight per day
mg/L	milligram(s) per liter
mg/m^3	milligram(s) per cubic meter
ml	milliliter(s)
MoE	margins of exposure
MOM	Ministry of Manpower
MSDS	Material Safety Data Sheet
MW	molecular weight
NAFTA	North American Free Trade Agreement

NCBW	National Control Banding Workshop
NGO	Non-Governmental Organizations
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
NORA	National Occupational Research Agenda
NRC/NAS	National Research Council, National Academy of Sciences
NSC	National Safety Council
OEB	occupational exposure band
OECD	Organization of Economic Cooperation and Development
OEL	occupational exposure limit
OES	Occupational Exposure Standard
OHS	occupational health and safety
OHSAS	Occupational Health and Safety Assessment Series
ORM	Occupational Risk Management
OSHA	Occupational Safety and Health Administration
PB-ECLs	performance-based exposure control limits
PECC	Pragmatic Exposure-Control Concentrations
PEL	permissible exposure limit
PIC	prior-informed-consent
POP	Persistent Organic Pollutant
POSITIVE	Participation-Oriented Safety Improvement by Trade Union InitiatiVE
PPE	personal protective equipment
ppm	parts per million
r2p	Research-to-Practice
R-phrases	risk phrases
REACH	Registration, Evaluation, and Authorization of Chemicals

Regetox	multiple-stage risk assessment strategy
RSC	Royal Society of Chemistry
RTECS	Registry of Toxic Effects of Chemical Substances
S-phrases	safety phrases
SARAH	System for Advising on the Regulations for Assessing Hazards
SME	small and medium enterprises
SQRA	Semi-Quantitative Risk Assessment
TLV®	Threshold Limit Value
TGS	Task Guidance Sheet
TTT	train-the-trainer
TWA	time-weighted average
UK	United Kingdom
UNCED	United Nations Conference on Environment and Development
UNITAR	United Nations Institute for Training and Research
VPPPA	Voluntary Protection Program Participants Association
WHO	World Health Organization
WHOCC	WHO Collaborating Centers Occupational Health Network
WIN-Asia	Work Improvement Network in Asia
WIND	Work Improvement in Neighborhood Development
WISE	Work Improvement in Small Enterprises
WMSD	work-related musculoskeletal disorders

GLOSSARY

control banding (CB): A strategy or process in which a single control technology (such as *general ventilation* or *containment*) is applied to one range or band of exposures to a chemical (such as 1−10 mg/m^3) that falls within a given hazard group (such as *skin and eye irritants* or *severely irritating and corrosive*). The following four main control bands have been developed for exposure to chemicals by inhalation:

Band 1: Use good industrial hygiene (IH) practice and general ventilation.

Band 2: Use local exhaust ventilation.

Band 3: Enclose the process.

Band 4: Seek expert advice.

This qualitative risk assessment and management approach focuses resources on exposure controls and describes how strictly a risk needs to be managed.

COSHH (Control of Substances Hazardous to Health) Essentials: A CB model developed by the United Kingdom Health and Safety Executive (UK HSE) to assist small- and medium-sized enterprises in complying with COSHH Regulations. The COSHH Essentials guidance is available in both a published document and in a Web-based model known as *e*COSHH Essentials.

KjemiRisk: Assessment of chemical health risk based on experience and practice in the Norwegian oil industry.

MAK: Maximale Arbeitsplatzkonzentration, or maximum concentration of a substance in the ambient air in the workplace which has no adverse effect on the workers' health as established by the Deutsche Forschungsgemeinschaft, the MAK-Kommission, and the German Ministry of Labor.

Occupational Risk Management (ORM): The process of using a combination of knowledge, training, and resources of IH practice to address hazards in the workplace. This process may encompass the use of a variety of toolbox (and within these, toolkit) approaches (defined below) including qualitative risk assessment and control-focused strategies to minimize hazardous exposures.

Toolbox: A toolbox is a collection of approaches for the control of worker exposures, and may be comprised of multiple toolkits. The toolbox concept is presented as a receptacle of various toolkits which can be used to address various workplace hazards associated with specific industries and tasks. As such, the toolbox provides a mechanism for occupational risk management, and is currently referenced as an ORM or CB toolbox. Examples of toolboxes with relevance for ORM in the United States include an environmental safety and health toolbox (i.e., broad), a Construction toolbox (industry-specific), and a Hair Dressers toolbox (occupation-specific).

Toolkit: A toolkit is a narrowly-defined, systematic solutions approach for the control of worker exposures focusing on a discrete task or series of tasks.

ACKNOWLEDGMENTS

This document was developed under the leadership of Paul Schulte, Ph.D., Director, Education and Information Division (EID). Thomas Lentz, Ph.D., was the project officer for this document, assisted in great part by Richard Niemeier, Ph.D., and Charles Geraci, Ph.D. The basis for this document was a report contracted by NIOSH and prepared by Deborah Imel Nelson, Ph.D. (Geological Society of America) and David M. Zalk (University of California, Lawrence Livermore National Laboratory). The following persons and organizations were especially helpful in providing assistance for the initial report: Jennifer Silk (OSHA, retired), Andrew Garrod (UK HSE), Paul Evans (UK HSE), the National Control Banding Workshop Organizing Committee, and the Risk Assessment Committee of the American Industrial Hygiene Association.

For contributions to the technical content and during the review of this document, the authors gratefully acknowledge the following NIOSH personnel (TO BE UPDATED):

Education and Information Division

Division of Applied Research and Technology

Division of Surveillance, Hazard Evaluations, and Field Studies
Aaron Sussell, Ph.D.

Office of the Director
Matt Gillen
Marilyn Fingerhut, Ph.D. (retired)

Division of Respiratory Disease Studies
Mark Hoover, Ph.D.

Health Effects Laboratory Division
Martin Harper, Ph.D.

Pittsburgh Research Laboratory

The authors wish to thank Jane Weber, Sue Afanuh, Anne Hamilton, Vanessa Becks, and Gino Fazio for their editorial support and contributions to the design and layout of this document.

Clerical and information resources support in preparing this document was provided by Lucy Schoolfield, Norma Helton, Rosmarie Hagedorn, and Laurel Jones.

Finally, special appreciation is expressed to the following individuals for serving as independent, external reviewers and providing comments that contributed to the development of this document: ***(To be updated with names of reviewers as reviews are received)***

Patrick Breysse, Ph.D., School of Public Health, Johns Hopkins University

Paul Hewett, Ph.D., EAS Solutions, Inc.

1 LITERATURE REVIEW

1.1 Challenges to the Traditional Occupational Exposure Limit (OEL) Approach

The traditional approach to protecting worker health was pioneered in the late 19th century, when the first OELs were established in Germany in 1886 or 1887 [Jayjock et al. 2000]. The American Conference of Governmental Industrial Hygienists (ACGIH®) published its first list of 148 exposure limits in 1946, then referred to as Maximum Allowable Concentrations and later re-named "Threshold Limit Values (TLVs®)" in 1956 [ACGIH 2007]. In the following decades, this quantitative approach was adopted by many of the industrialized nations, and as a result contributed to the improvement of working conditions, increased span and quality of life for countless workers, and decreased compensation costs. As a case in point, the U.S. Department of Labor, Bureau of Labor Statistics records for occupational injuries and illnesses since the advent of the Occupational Safety and Health Administration (OSHA) indicate a reduction from 10.9 cases per 100 workers in 1972 to 6.1 in 2000 [Swuste and Hale 1994; NIOSH 2002, 2004]. Despite these contributions to worker health, this approach has been hampered by limited resources to conduct toxicological and epidemiological research to establish the OELs, additional resource limitations for performing routine, periodic monitoring for exposure assessment and evaluation of controls, as well as legal challenges to the standards development process.

In recent decades, the limitations of the traditional approach to protecting worker health—i.e., sampling and analysis of airborne contaminants and comparison of results with OELs—have become apparent. Factors such as the increasing number of hazardous chemicals in commerce, insufficient toxicological and epidemiological data, and recognition of the large variability in exposure measurements, both within and between workers, have led occupational safety and health practitioners to consider additional solutions. These pressures contributed to innovative qualitative and semi-quantitative approaches to protecting worker health.

The challenge of protecting worker health persists and expands, with an increasing number of hazardous chemicals in production, commerce, and use in the United States and worldwide, for which OELs have not been established. As many as 170,000 chemicals may require registration under the European Commission regulations known as the Registration, Evaluation and Authorisation of Chemicals (REACH) [Money 2003]. Gardner and Oldershaw [1991] indicated that in the European Economic Community, only about 1,000 OELs have been established for chemical substances, with the United Kingdom (UK) Health and Safety Executive (HSE) having OELs for ~ 600 substances [Topping et al. 1998]; yet more than 100,000 substances are traded in the European Community [EINECS 1987]. As an additional complicating factor, early surveys within the UK by the HSE indicated that most small and medium enterprises (SMEs) were not able to comply with the Control of Substances Hazardous to Health (COSHH) regulations, mostly due to insufficient knowledge and resources [Topping et al. 1998]. The problem is equally daunting in the United States. In his opening address at the 2nd International Control Banding Workshop [Howard 2004], the National Institute for Occupational Safety and Health (NIOSH) Director Dr. John Howard provided figures from the International Task Force 40, Industrial Chemicals—Operational and Medical Concerns:

> As of 01 January 2003, the American Chemical Society (ACS) Chemical Abstracts Service (CAS) Registry contained 17,688,891 organic and inorganic substances and 12,072,228 biosequences. The CAS Online Chemical Catalogs File contained data on

> 1,343,277 commercially available chemicals and their worldwide suppliers while the CAS Regulated Chemicals Listing Database has data on 224,787 inventoried/regulated substances. The Organization of Economic Cooperation and Development (OECD) List of high production volume (HPV) chemicals contains 5,234 chemicals that are produced or imported into OECD countries in excess of 1,000 tons per year. The 2000 United States, Canada, Mexico Emergency Response Guidebook lists about 2,500 individual chemicals and classes of chemicals that are shipped in North America.

These statistics speak to the challenges for establishing and implementing quantitative OELs given limited resources and data. Particularly in SMEs and the less-developed and newly industrializing countries, applying quantitative OEL approaches may not be adequate for protecting workers from chemical exposures.

As a result of these challenges, individual companies, trade associations, and government agencies have developed innovative approaches to protecting both worker health and the environment. The chemical industries provided an early example of qualitative/semi-quantitative methods to assess safety and health risks from catastrophic failures at major chemical facilities [Money 2003]. Another example is the shift within the pharmaceutical industry from use of air and wipe sampling to document worker exposure, to the use of air and wipe sampling to verify the effective operation of controls. Environmental monitoring thus assumes the role of documenting the results of the risk assessment cycle [Tait 2004]. Building upon this understanding of some of the factors influencing the development of qualitative risk management and control banding (CB) approaches, the following section will trace the origins of these developments in some of the earliest qualitative and semi-quantitative models and methods.

1.2 The Origins of CB for Chemical Agents

CB grew out of the qualitative and semi-quantitative approaches that have been practiced as a complement to the traditional model of air sampling and analysis. The earlier CB strategies were based on the concept that although there are many chemicals to which workers can be exposed, there are only a few (generally 4 or 5) categorical approaches to protecting workers. These strategies linked the hazard of a chemical substance, usually determined by a simple measure of toxicity, to a suite of control measures.

CB has its roots in a number of qualitative and semi-quantitative risk assessment approaches that began to appear in the 1970s [Money 2003; Lewis 1980; AIChE 1994]. An example of one such approach is a risk matrix describing the likelihood and probable severity of event, e.g., explosion or release of toxic material, developed for use by a chemical company. Examples of key elements in evolution of relevant strategies are presented in Table 1. Similarities are evident in these strategies, as elements of these approaches were borrowed from each other and built upon previous efforts [Money 2003], with professional exchanges of information and ideas among occupational health practitioners and scientists in the pharmaceutical and chemical industries, governmental agencies, and professional and trade associations. Consequently, it is not always possible to trace a straight-forward progression by relying on chronological appearance in the peer-reviewed literature. A discussion of key components and contributions follows.

Table 1. Key elements in the evolution of qualitative occupational risk management and CB* concepts and their references in the literature

Element(s)	References
Safety risks from major facilities: risk matrices combining severity and frequency of event	ICE 1985; AIChE 1992
Simplified approach to workplace health risk assessment (COSHH)	HMSO 1988
Application of safety risk concepts to workplace health (in laboratories): (1) categorization of hazard using R-phrases, (2) simple approach to estimate exposure in laboratories or a workplace risk matrix using both to identify appropriate control solutions	RSC 2003; Money 2003
Health risk assessment for laboratories	RSC 2003, 1996
Use of hazard ratings to prioritize IH monitoring, install engineering controls, select PPE, etc.	Henry and Schaper 1990
Relationship between R-phrases and OELs	Gardner and Oldershaw 1991
Use of carcinogenic ranking of aromatic amines and nitro compounds to suggest practical workplace controls	Gardner and Oldershaw 1991; Crabtree et al. 1991; Money 1992a; CIA 1993
Application of the RSC approach beyond laboratories, e.g., the pharmaceutical industry; these strategies use R-phrases and simple algorithms to estimate exposures, and combine both to suggest controls; representing the "first use of CB concepts for wider use in industry" [Money 2003]. These sector-specific approaches developed the idea that hazard classification could provide a basis for generic exposure control standards [Money 2003], and went beyond original categorization of carcinogens to include other toxic endpoints (e.g., CIA [1993]). (Note: Approaches used in the pharmaceutical industry now include lacrymators, highly toxic substances, reproductive hazards, irritants, sensitizers, and mutagens [Tait 2004].)	Naumann et al. 1996; Money 1992a; CIA 1993
Application for specific product classes and families, allowing more detail in a more limited setting (ranking of carcinogens, and linking with facility design and safe handling guidelines)	CIA 1992; Money 1992b
Health risk assessment for product classes and families. The CIA [1993] includes a table for colorants that includes hazard category (14), hazard classification (e.g., toxic, corrosive), associated R-phrase, and guideline control level (8-hour TWA), and a separate set of recommendations for each hazard category.	Naumann et al. 1996; CIA 1993; HSE 2001
Setting OELs and OEBs for pharmaceutical agents	ABPI 1995
Further development of RSC approach	RSC 2003

(Continued)

Table 1 (Continued). Key elements in the evolution of qualitative occupational risk management and CB* concepts and their references in the literature

Element(s)	References
Additional proposals for generic OELs or control approaches based on hazard categorization	ABPI 1995; CIA 1997; TRG 1996]
Marketed chemicals in general	Russell et al. 1998; Brooke 1998; Maidment 1998; HSE 1999, 2000, 2001
Health risk assessment for industry	HSE 1999; IOM 2005
Safety, health, and environmental risk assessment for users of chemicals	UIC 1999
Approaches to the tiered and targeted risk assessment of chemicals	ECETOC 2002
WISE	ECETOC 2002
WIND	ECETOC 2002

Adapted from Money [2003].
*Abbreviations: CB=control banding; CIA=Chemical Industry Association; COSHH=Control of Substances Hazardous to Health; OEB=Occupational Exposure Band; OEL= occupational exposure limit; PPE=personal protective equipment; R-phrases=Risk Phrases; RSC=Royal Society of Chemistry; TWA=time-weighted average; WIND=Work Improvement in Neighborhood Development; WISE=Work Improvement in Small Enterprises.

1.2.1 Core Principles

According to Money [2003], one basic tenet for CB was the need for consistent, accurate results among different risk assessors that could be used by nonexperts. Identifying key exposure determinants without reliance upon sophisticated sampling methods is an important step towards satisfying this requirement. In addition, other characteristics which have come to be associated as core CB principles are listed below:

1. Approaches must be understandable (by users and by those affected) to facilitate risk evaluation and communication.
2. The required information must be readily available to the user, particularly SMEs (e.g., provided on safety data sheets).
3. The output must be practical advice.

4. The approach must be user-friendly.
5. Users must have confidence in the approach and the output it provides.
6. Output must be provided in a transparent and consistent way.

1.2.2 Comparison of OELs to R—phrases*

A key component of a CB model is the ability to categorize easily the toxicity of substances, using readily available information. Using toxicological data for a substance, an appropriate risk phrase (R-phrase) is assigned to indicate the relative hazard posed by exposure to the substance via a given route. (Origins of the R-phrases are described in Section 1.2.4, and the reference for criteria for their assignment is cited in the footnote below.) Gardner and Oldershaw [1991] presented a comparison of the American (ACGIH TLVs®) and German OELS to the designated risk R-phrases for volatile organic substances [EEC 1987]. They found that the distributions of the OELs for substances consistent with grouping by R-phrase 23 (toxic by inhalation) and R-phrase 26 (very toxic by inhalation) best fit a log-normal distribution, and that the means for both R-phrase groups were not significantly different. They concluded that the R-phrases, while emphatically not OELs, could be referenced as Pragmatic Exposure-Control Concentrations (PECCs) and applied as guides to control inhalation exposure when other information was lacking. Gardner and Oldershaw [1991] suggested that this guidance would be useful in cases where toxicological data on substances were incomplete, or the ability to understand such data was limited.

* "The EU classification system and the classification criteria are defined in Annex VI to the Dangerous Substance Directive (67/548/EEC), as amended by the Seventh Amendment (92/32/EEC). Annex I of the Dangerous Substance Directive provides standard phrases (R-phrases) indicating the special risks arising from the dangers involved in using the substance." [Tischer 2001a].

Tischer [2001a] noted that the assignment of R-phrases to hazard bands, described below, was still being debated in Germany in 2001, and might well result in a different model than the HSE categorization.

1.2.3 Establishing In-House OEBs

COSHH regulations on inhaled substances that do not have assigned maximum exposure limits (MELs) or Occupational Exposure Standards (OESs) require employers to control exposures to "a level to which nearly all the population could be exposed, day after day, without adverse effects on health" (quoted by the Association of the British Pharmaceutical Industry [ABPI, 1995]) as paragraph 38 of the General Approved Code of Practice, no date provided; currently Paragraph 126 of the Approved Code of Practice and Guidance [HSE 2002a]). To assist its members in meeting this requirement, the ABPI published *Guidance on Setting In-House Occupational Exposure Limits for Airborne Therapeutic Substances and their Intermediates* in 1995. The pharmaceutical industry has typically been faced with many situations in which there are insufficient data to develop OELs [ABPI 1995]:

1. during new-product development,
2. for intermediate products, and
3. for products with limited pharmacological and toxicological data.

The level of exposure guidance recommended (i.e., OEB or OEL) would thus vary with the stage of product development and toxicity testing. ABPI guidance envisioned that the process of setting OELs might begin with consideration of an OEB at the end of the research and development phase, when short-term toxicity and in-vitro tests had been completed. It would continue with refinement of the OEB or development of a health-based OEL at the transfer-to-production stage, when longer-term toxicity, pharmacological, and clinical tests had been completed. Review and confirmation of the OEL would occur at the routine manufacturing phase.

ABPI suggested categorization for OEBs with four discrete bands as shown in Table 2. ABPI allowed that a different number of bands might be appropriate; e.g., more may be appropriate when working with more potent compounds. Substance assignments would not need to be at the top of a band, but anywhere within the band considered appropriate. Accumulation of more data could result in the later establishment of an OEL.

Table 2. OEBs with target ranges of exposure*.

OEB	Vapors (ppm)	Dusts (mg/m^3)
A	10–500	1–5
B	1–10	0.1–1
C	0.1–1	0.01–0.1
D	<0.1	<0.01

*Abbreviations: OEB=Occupational exposure band; ppm=parts per million; mg/m3=milligrams per cubic meter.
Source: ABPI 1995.

1.2.4 Linking Toxicological Data with Appropriate Levels of Control

In an early report linking toxicological data to an appropriate level of control, Money [1992b] presented a structured approach to design and operation of a fine chemical plant, based on a carcinogenic ranking system for aromatic amines and nitro compounds. This was a broad approach for ensuring that appropriate measures would be in place to control risks from these chemicals from both routine and abnormal operations; however, it did not provide specific solutions and controls. Money suggested that the approach, which covered both inhalation and skin contact, should be applicable to similar approaches ranking relative hazards of chemicals [Henry and Schaper 1990; Gardner and Oldershaw 1991; Woodward et al. 1991].

The approach described by Money used four categories of carcinogenic potential, collapsed for simplicity from a system using six [Crabtree et al. 1991], which considered both carcinogenic potency and weight of evidence. Money argued that while it is important to distinguish the potencies of different substances, in reality such a separation is artificial and impractical. For these four levels of carcinogenic potency, four levels of controls were identified, progressing in their complexity and stringency, with each level building on the previous. After consideration of eliminating known carcinogenic substances or substituting safer alternative substances, the following levels would be used for the various levels of carcinogenicity.

- **Level 1:** For all chemicals (regardless of carcinogenic potential), good basic IH practice, with a plant built to sound industrial standards.
- **Level 2:** For suspected animal carcinogens of low to moderate potency, greater reliability and integrity than Level 1, plus containment of the plant (or isolation of specific processes) by physical or procedural measures, and possibly with health management systems.
- **Level 3:** For suspected human carcinogens with slight carcinogenicity to animals, or proven or suspect animal carcinogens, at moderate and low doses respectively, a segregated plant with detoxification, high reliability and containment, and regular technical audits.

- **Level 4:** For proven human, suspect human/highly carcinogenic to animals, or proven or suspected animal carcinogens, at low to very low doses, respectively, an automated plant with bulk or semi-bulk transfers, process control, and plant audits.

These concepts were applied for exposures to pharmaceutical active ingredients in laboratory and manufacturing operations by Naumann et al. [1996]. The pharmaceutical industry had traditionally used risk assessment methods to establish OELs for active ingredients. However, the increasing potency of these agents, difficulties in establishing *no effect* levels for certain products, and challenges in sampling and analyzing contaminants at very low exposure levels led to a new approach. On the basis of the biosafety level concepts used in laboratories, and substantiated by a large database of air monitoring data for various operations, Naumann et al. [1996] distinguished five hazard categories (performance-based exposure control limits [PB-ECL]), based on toxicological and pharmacological properties of these agents. Compounds were then placed into one of these five categories based on the pharmaceutical active ingredients and on the engineering controls and administrative procedures known to be effective in controlling exposures to the necessary level.

The same concepts—linking hazard category (1–4), hazard classification (e.g., toxic, corrosive), associated R-phrase, guideline control level (8-hour TWA), and recommendations for each hazard category—were further explored by the CIA [1993] in their guidelines for safe handling of colorants (second version). However, at the time of that exploration no one had yet factored the probability of exposure into the risk assessment and risk management equation.

Guest [1998] described the CIA influence as follows:

> The UK Chemical Industries Association scheme described here [CIA 1997] sets out a concept of hazard categorization leading to the placement of substances into Occupational Exposure Bands. The more recent work has taken the concept forward to link hazard categorization and exposure banding with structured guidelines for control of occupational exposure.

According to Guest, the advice of the COSHH Approved Code of Practice, i.e., to set a self-imposed working standard for chemicals that did not have an official OEL, could not be followed by industry or government, due to the technical complexity of establishing OELs, the lack of adequate toxicological databases and experts, and the sheer volume of substances covered in the European Inventory of Existing Commercial chemical Substances (EINECS) [1987]. These factors led the CIA to develop chemical categorization guidelines for their member organizations.

Building on the earlier CIA [1993] guidance and the work of Gardner and Oldershaw [1991], the later CIA [1997] guidelines incorporated the Chemical Hazardous Information and Packaging (CHIP) R-phrases and guideline control levels, in addition to data on adverse effects in humans (see Table 3). The purpose of these guidelines was to provide a simple, broad-based, integrated approach for use by CIA members in classifying hazards. The categories were to be called OEBs, and would only be developed when there were no other in-house, national, or international OELs. They would define the upper limit of acceptable exposure. As the number of control strategies (CSs) is usually limited to perhaps three or four levels, this approach was designed to cover six orders of magnitude, plus a special category (see Table 4). The upper limits (OEB C for dusts, OEB D for gases/vapors) were designed to *reflect good occupational hygiene practice* and the maximum dust concentration (i.e., 10 mg/m^3) in the COSHH regulations.

Table 3. Selected criteria for assignment of dust to OEBs* (based on Guest [1998]).

OEB	Selected Criteria for Substances†
Category X	R45, R46, R49: should be handled according to COSHH Carcinogens ACoP‡
(Special considerations)	Respiratory and skin sensitizers (R42, R43)
	Substances showing adverse effects in humans at low doses: <0.05 mg/m^3 by inhalation or <0.01 mg/kg/day
OEB A	Toxic to reproduction (R60, R61)
	Very toxic (R26, R27, R28)
OEB B	Toxic to reproduction (R62, R63)
	Toxic (R23, R24, R25, R48)
	Unknown toxicity not assigned to higher OEB
OEB C	Harmful (R20, R21, R22, R48)
	Dust not allocated to higher OEB

*Abbreviations: ACoP=Approved Code of Practice; COSHH=Control of Substances Hazardous to Health; OEB=occupational exposure band.
†This rating system is opposite that used in the COSHH Essentials ratings.
‡Approved Code of Practice, current edition is from HSE [2002a].

Table 4. OEBs*

	Gases and vapors	Dusts
Category X	Special considerations	
OEB A	< 0.5 ppm	<0.1 mg/m^3
OEB B	0.5–5 ppm	0.1–1 mg/m^3
OEB C	5–50 ppm	1–10 mg/m^3
OEB D	50–500 ppm	Not applicable

*Abbreviations: OEB=occupational exposure bands; ppm=parts per million; mg/m^3=milligram(s) per cubic meter. [Guest 1998; CIA 1997]

The main selection criteria for assignment to the bands were the CHIP R-phrases, which were readily available in the United Kingdom, and additional information about adverse effects in humans. Classification was based on the most sensitive endpoint for which data are available. Table 4 summarizes the criteria, derived from a more comprehensive table from Guest [1998].

In conclusion, Guest stressed the need to consider (1) re-classification of substances if/when more data became available, (2) other routes of exposure, and (3) requirements for health surveillance and occupational hygiene measurements for substances with limited toxicological data. In particular, Guest commented on the need for testing to "provide a high degree of confidence in the OEBs predicted." In examining the relationship between OEBs and OELs, it was found that "the majority of substances . . . were correct to an order of magnitude and that, for approximately five percent of the substances reviewed, the OEB was less stringent than the OEL." Guest suggested that the possibility of the latter observation was acceptable due to the margin of safety built into most OELs, and that the OEB guideline values were preferable to inadequate standards of control.

1.2.5 Exposure Assessment

Although it had not yet been incorporated into the equation, much work was being conducted during the 1990s on predicting exposures. For example, Burstyn and Teschke [1999] reviewed 13 experimental and 32 observational studies describing methods for studying exposure determinants. Exposure determinants identified in the studies included work tasks, equipment used, environmental conditions, and existing controls. Little attention was devoted to volume of product used and less to the physical characteristics of chemicals in use. The exposure determinants studied were classified as factors that

4. directly increase exposure, e.g., processes producing airborne contaminants
5. directly decrease exposure, e.g., local exhaust
6. affect exposure indirectly, e.g., work location.

Another example of early consideration of exposure determinants in a risk management model is the Stoffenmanager (described more fully below), which approaches the use of exposure assessment in a banding strategy [Tijssen et al. 2004]. In evaluating the risk, a dedicated exposure model [Cherrie and Schneider 1999] is used to provide a subjective exposure assessment based on a systematic consideration of descriptive workplace activities and environment. Applying this model, the subjective exposure assessments showed significant correlation with analytical exposure measurements across 63 jobs and different agents (asbestos, toluene, mixed respirable dust, and man-made mineral fibers).

1.2.6 Hazard and Exposure: Determinants of Risk and Control Strategies

The concepts and principles that had been developing since the 1970s were combined in the late 1990s to result in a simple but powerful concept:

Health Hazard + Exposure Potential → Generic Risk Assessment → CS

This equation indicates that information about the health hazard and exposure associated with a chemical substance and its use can be used to perform a qualitative risk assessment and determine the appropriate risk management or control strategy.

The UK HSE played a pivotal role in developing a regulatory approach based on these concepts [Russell et al. 1998; Brooke 1998; Maidment 1998]. While the work of the HSE was based in large part on the strategy of the UK CIA [Guest 1998; CIA 1997] (i.e., categorizing substances into occupational exposure bands), it is apparent that many other groups have contributed to the development of COSHH Essentials. Based on consideration of the membership lists of the various task forces convened by groups like the CIA and the UK HSE, and the authorship of many of the articles included in this review, there was much communication within professional circles regarding qualitative and semi-quantitative approaches to protecting worker health.

1.3 The UK Experience: COSHH and the COSHH Essentials Strategy

In the late 1980s, the UK HSE passed COSHH regulations, requiring among other things, employers to perform risk assessments for all chemicals used in the workplace [HMSO 1999, 2002]. Despite much optimism that these regulations would "bring greater emphasis on the assessment of risks to health in industry" [Parker 1989], there were many challenges to their effective implementation [Winterbottom 1987]. Seaton [1989] reported on an unpublished survey of 2,000 companies taken shortly after COSHH promulgation that showed "widespread ignorance of the new regulations and their implications among smaller concerns . . . ." On a positive note, Molyneux and Wilson [1990] described the program their employer had developed to meet the requirements of COSHH. However, there were frequent reports on the deficiencies and needs of many workplaces in complying with COSHH, particularly in health care settings [Hutt 1994; Menzies 1995; Fraise 1999; Barker and Abdelatti 1997; Cooke et al. 1991; Harrison 1991; Waldron 1989; Aw 1989]. These authors stressed necessary but difficult requirements to inform and train staff, evaluate risks, monitor exposures, and implement control measures. Similarly, Palmer and Freegard [1996] reported that despite the number of sensitizing agents present, relatively few hairdressing establishments had attempted to comply with the 1988 COSHH regulations, and Loughney and Harrison [1998] found problems with contact dermatitis in hydrotherapy pools due to inappropriate application of COSHH risk assessment principles. Harrison and Sepai [2000] criticized COSHH, pointing out that COSHH is focused on the role of inhalation as a route of exposure in the workplace to the exclusion of other routes (i.e., dermal), and suggesting that biomarkers can and should play an important role in surveillance of workers' exposure to metals and organic chemicals.

In an effort to understand better the problems with implementation of COSHH, UK HSE conducted market research to characterize industry's perception of OELs and the degree to which decisions on control measures were affected by OELs [Topping et al. 1998; Tischer 2001b]. A survey was conducted of 1,000 randomly selected chemical users and 150 safety and health representatives of trade unions who were interviewed by telephone about chemical use, sources of information, risk management, and understanding of COSHH and OELs. The majority (75%) of respondents were from small firms (<10 workers), mirroring the make-up of British industry; although the majority of trade union representatives were from firms with >100 workers. Findings included the following:

1. Decisions on control measures were based largely on information from suppliers and on personal experience.
2. Most respondents took measures to protect workers, primarily by PPE, followed by process controls. This indicates that failure to comply results more from lack of knowledge than from lack of will to meet the requirements.
3. Only 35% of the respondents were aware of COSHH; only 19% truly understood OELs.

4. Trade union representatives tended to have greater understanding than the chemical users from small firms.
5. While larger chemical companies and occupational safety and health professionals understand the COSHH requirements, "many small firms wanted to be told exactly what they need, and do not need, to do" [Topping 2001].

What is COSHH Essentials?
The most fully developed CB chemical assessment model comes from the UK HSE and is known as COSHH Essentials (from COSHH regulations). It was designed to help SMEs do risk assessments for chemicals and mixtures of chemicals that employers were required to perform under COSHH Regulations. The basic idea is that while thousands of chemicals are manufactured and used in commerce, only a few levels of risk management (control bands) are available to control worker exposures to these chemicals. It helps the user conduct a simple risk assessment based on the following: • The type of task being performed • The hazard of the chemical substance, which is assigned to Hazard Band A–E • The volatility (3 levels) or dustiness (3 levels) of the chemical substance • The quantity of the chemical substance used in the task (3 levels) The system steps the user through a simple matrix that indicates the appropriate level of risk management or control band required based on this information. It then provides specific guidance in the form of a Control Guidance Sheet (CGS) for the task being conducted and the recommended control band based on the 4-level strategy outlined above. COSHH Essentials is available in paper format or in electronic database format as a simplified approach on the Web at www.coshh-essentials.org.uk.

Topping et al. [1998] concluded that given the widespread lack of understanding and sphere of influence of OELs, generation of additional lists of OELs would not be cost effective and that OELs should be limited to widely used substances of concern. Consequently, these authors called for a reappraisal of the OEL system, while at the same time recognizing that OELs along with additional information (e.g., physical properties and use) could be used to recommend appropriate control measures.

The problem was even more acute for micro-enterprises (<5 workers) according to Oldershaw [2003] who noted the following:

- Micro-businesses are not just smaller versions of larger businesses, as they cannot have the occupational safety and health skills that big business can afford.
- OELs may be of no practical use to micro-business.
- Decision-makers in micro-business tend to rely more on chemical suppliers for support and guidance.
- Measurement of workers' exposure to chemicals is usually not possible due to cost, lack of availability, and difficulty in interpretation and application.

These findings likely apply to economic markets in the United States, as the employment composition of U.S. businesses is similar to that in the United Kingdom. In the United States, 98% (6.3 million establishments) of businesses have fewer than 100 workers with more than half (56%) of the American workforce being employed in these SMEs [NIOSH 1999]. In the United Kingdom, of the 3.8 million businesses, 99% have less than 200 workers; 69% are self-employed; and 20% have 1 to 4 workers [Anfilogoff 2004]. Furthermore, one third (34%) of UK businesses use chemicals, and 47% are uncertain of ways to get applicable compliance information. In the European Union (EU) overall, 99% of all businesses have fewer than 50 workers [EASHW 2005].

The UK HSE was faced with the realizations that a large number of chemical substances are manufactured and used for which OELs would never be developed, and also that the majority of SMEs did not understand and did not have the resources to meet COSHH requirements to conduct risk assessments for chemicals used in the workplace [Topping et al. 1998; Menzies 1995; Palmer and Freegard 1996]. In response, the HSE established a working group of key stakeholders to develop a simple system of generic risk assessment [Topping 2001]. This approach, which leads to selection of appropriate controls, was first published as *COSHH Essentials: Easy Steps To Control Chemicals* [HSE 1999].

In 1998 the UK HSE published a series of papers outlining a CB strategy in which the hazard was combined with the potential exposure to determine a recommended level of control approach. EU R-phrases were used to rank the hazard of a chemical, and potential for exposure was estimated by the quantity in use and the volatility/dustiness of liquids or solids, respectively.

As described above, the growing realization on the part of the UK HSE that the traditional model was beyond the reach of the SMEs led to the development of a CB chemical assessment model known as COSHH Essentials. Much of this developmental work was conducted by a working group established by the UK Health and Safety Commission's Advisory Committee on Toxic Substances [Topping 2001]. A series of articles on the "UK Scheme to Help Small Firms Control Health Risks from Chemicals" explained the basic concepts [Russell et al. 1998], the toxicological considerations [Brooke 1998], and occupational hygiene considerations [Maidment 1998]. The editor-in-chief of the *Annals of Occupational Hygiene* introduced these articles with an editorial preface entitled "The sunset of exposure limits – and the dawn of something better? [Ogden 1998]"

1.3.1 Basic Concepts

The challenge facing HSE was to develop guidance that was practical for SMEs, based on readily available hazard information, and was easy to use and understand. Figure 1 illustrates the general pattern of processing hazard information to derive appropriate control approaches, a pattern associated with the HSE model [Russell et al. 1998]. The model describes using R-phrases and simple predictors of exposure to conduct a generic risk assessment, which leads to straightforward recommendations on risk management (i.e., control approaches).

Health hazard	**+ Exposure potential**	**→ Generic risk assessment**	**→ Control approach**
Substances allocated to a hazard band using R-phrases	Substances allocated to a dustiness or volatility band and a band for the scale of use	Combination of health hazard and exposure potential factors determine desired level of control	Type of approach needed to achieve adequate control

Figure 1. Factors used in HSE's core model [Russell et al. 1998].

The COSHH Essentials, as the evolving HSE CB model was named, builds on earlier approaches [Naumann et al. 1996; CIA 1992, 1997; RSC 2003; Gardner and Oldershaw 1991; Money 1992a,b] but adds two significant developments: it is specifically developed for SMEs and it includes control advice. Because COSHH Essentials is limited to substances classified under CHIP, the model is not applicable to pesticides and pharmaceuticals as well as process-generated hazards such as wood dust, and welding fumes. (Silica dust is also excluded, but has been addressed more recently with the HSE development of the Silica essentials.) The key components of the model include the hazard banding, exposure potential, and control approaches. Hazard banding is described more fully below [Brooke 1998]. Exposure banding is a function of the physical properties of a substance and the likelihood of the substance to become airborne (volatility of liquids or dustiness of solids, and the quantity in use [Maidment 1998]). These elements are combined to determine the appropriate control approach (see Figure 2). Later versions of COSHH include PPE Essentials, offering advice for gloves, respirators, and addressing dermal risks. Another feature of the COSHH Essentials Web site is the newer Direct Advice topics for accessing hazard guidance by specific tasks, services, and processes (e.g., foundries, woodworking, beauty treatments, pubs, clubs, and restaurants).

Control Approach 1—General ventilation. Good standard of general ventilation and good working practices.
Control Approach 2—Engineering control. Ranging from local exhaust ventilation to ventilated partial enclosure.
Control Approach 3—Containment. Containment or enclosure, allowing for limited, small scale breaches of containments.
Control Approach 4—Special. Seek expert advice.

Figure 2. Control approaches used in COSHH Essentials (see Russell et al. [1998]).

The developers felt that operation-based CGS would provide the best format for advising SMEs. As of September 2007, approximately 300 CGS had been developed, including COSHH Essentials, Silica Essentials, and others. Each CGS is structured according to a standard format, and contains sections on workplace access, design and equipment, maintenance, examination and testing, cleaning and housekeeping, PPE, training, supervision, a short list of references, a sample schematic of an engineering control, and a worker checklist for proper use of controls.

A key point from Russell et al. [1998] should be quoted directly:

> However, the use of the scheme will not in itself constitute a suitable and sufficient workplace risk assessment as required by regulation 6 of COSHH. Employers should still consider other factors in their risk assessments, such as the need for health surveillance and the need to monitor exposure to ensure adequacy of control. Similarly, they will want to consider the suitability of the controls recommended by the scheme for their particular work situation. The scheme is therefore guidance to aid employers' risk assessment and selection of control measures, not a replacement for it . . . .

They also pointed out that it is easy to focus on COSHH Essentials guidelines and to lose sight of an important reminder: the COSHH Approved Codes of Practices suggest substitution as a means of preventing exposures. Russell et al [1998] recognized that an over-protective approach would lack credibility and deter promotion efforts and implementation. On the other hand, an under-protective approach would not protect workers. Weighing these factors, it was generally agreed in the model development that a conservative approach (i.e., slightly overprotective) would be the most responsible.

1.3.2 Toxicological Considerations [Brooke 1998]

Brooke [1998] outlined the following criteria for the toxicological basis of the UK approach:

1. It had to be simple and transparent so that it would be understandable and consistently used by SMEs.
2. It had to make the best use of available hazard information.

3. The recommended control strategies had to vary according to degree of health hazard of a substance.

The R-phrases that are agreed upon throughout the EU facilitated these criteria, as they address all relevant toxicological endpoints. This idea had been proposed previously [Gardner and Oldershaw 1991] and had formed the basis of similar strategies [ABPI 1995; CIA 1997; RSC 2003]. Brooke noted three differences between these approaches and that of the UK HSE:

1. COSHH Essential includes alignment between dust and vapor target exposure ranges and the approach taken to relate target exposure ranges to dose level cut-off values ensures adequate margins between exposure and health effect levels for dusts and vapors.
2. COSHH Essentials is based on achievement of exposure levels anywhere in the target range, whereas the CIA recommends that exposures should be maintained "as low as reasonably practicable" [(ABPI 1995; Guest 1998; CIA 1997].
3. The COSHH Essentials approach was evaluated by comparison to health-based OELs (the CIA approach was also evaluated per Guest [1998]).

Brooke's article achieved two goals: (1) it explained the assignment of R-phrases to the Hazard Bands A-E used in the COSHH Essentials and (2) it compared these assignments with health-based OELs. Each hazard band, which is based on toxicological considerations, covers a log (10-fold) concentration range. As the relationship between the part per million (ppm) concentration of a vapor and the mg/m^3 concentration is a function of its molecular weight (and also temperature and pressure, though not discussed in this article), the working group who oversaw development of this chemical classification decided to adopt a pragmatic approach and to align the exposure bands as seen in Table 5. However, it must be noted that due to this alignment, "in mg/m^3 terms, the concentration range for substances in vapor form is substantially higher than that for the substance in particulate form, for the same toxicological hazard band."

Table 5. Allocation of R-phrases* to hazard bands (see Brooke [1998]).

Hazard band	Target airborne concentration range (Note 1)	R-phrases
A	>1–10 mg/m^3 dust; >50–500 ppm vapor	R36, R38, all dusts and vapors not allocated to another band (Note 2)
B	>0.1–1 mg/m^3 dust; >5–50 ppm vapor	R20/21/22, R40/20/21/22
C	>0.01-0.1 mg/m^3 dust; >0.5–5 ppm vapor	R48/20/21/22, R23/24/25, R34, R35, R37, R39/23/24/25, R41, R43
D	<0.01 mg/m^3 dust; <0.5 ppm vapor	R48/23/24/25, R26/27/28, R39/26/27/28, R40 Carc. Cat. 3, R60, R61, R62, R63
E	See specialist advice	R40 Muta. Cat. 3, R42, R45, R46, R49
S: skin and eye contact	Prevention or reduction of skin and/or eye exposure	R34, R35, R36, R38, R41, R43, Sk (Note 3)

*Abbreviations: ppm=parts per million; R-phrases=Risk Phrases; mg/m^3=milligrams per cubic meter.

Brooke described the principles and procedures used to allocate substances into hazard bands; (for more detail, see Brooke [1998]). In general, allocation is influenced by presence of an identifiable dose threshold, seriousness of the resultant health effect, and relative exposure level at which toxic effects occur. If a substance has more than one R-phrase, the R-phrase leading to the highest level of control governs. See Appendix B for a more detailed explanation of allocation of vapors to hazard bands.

Regarding evaluation of COSHH Essentials, Brooke [1998] reported on the comparison of the R-phrases and resulting target airborne concentrations to the relevant health-based OELs on national lists (UK and German MAK values). The appropriate R-phrase for each substance was determined, using the R-phrases leading to the most stringent controls, and representing the same endpoint used for the OEL. This comparison was conducted for 111 substances with recent, scientific-based OELs from the UK and MAK, and identifiable thresholds (thus excluding Hazard Band E). (See Table 6.) Regarding dusts, for 33 substances (100%), the OEL was within or higher than the target airborne concentration range of the hazard band. For vapors, for 76 substances (97%), the OEL was within or higher than the target airborne concentration range. Only 2 vapors had target ranges above the OEL. For one (diproplyene glycol monomethyl ether [DPGME]), the OEL of 50 ppm was on the border between bands A and B. The second (methyl ethyl ketone peroxide [MEKP]) has a very small toxicological database, and the OEL was established based on analogy. While concluding that the R-phrases can be used effectively to allocate substances to hazard bands, Brooke stresses that the process is not intended as a replacement for the health-based OEL setting process.

Table 6. Overall results for comparison of COSHH* Essentials hazard bands with health-based OELs, using all hazard bands [Brooke 1998].

	Dusts	Vapors	Total
Number of substances	33	78	111
Number for which OEL lies within target airborne concentration range of hazard band	14 (42%)	44 (56%)	58 (52%)
Number for which OEL is higher than target airborne concentration range of hazard band	19 (58%)	32 (41%)	51 (46%)
Number for which OEL is lower than target airborne concentration range of hazard band	0 (0%)	2 (3%)	2 (2%)
Number for which scheme recommends control equivalent to or better than that required by OEL	33 (100%)	76 (97%)	109 (98%)

*Abbreviations: COSHH=Control of Substances Hazardous to Health; OEL=occupational exposure limit.

Concerns have been raised about the accuracy of the EU classification of chemical substances [Ruden and Hansson 2003]. In a comparison of EU classifications for acute oral toxicity for 992 substances to those available in the Registry of Toxic Effects of Chemical Substances (RTECS), Ruden and Hansson found that 15% were assigned too low a danger class and 8% too high. They were unable to determine the cause due to insufficient transparency of the process. It should be noted that RTECS is merely a registry and does not necessarily provide an evaluation of chemical toxicity.

One essential point regarding the proper use of the COSHH Essentials approach is cited by Brooke [1998] as follows:

> Given that the toxicological basis which underpins the scheme relies on the use of R-phrases as the indicator of toxicological hazard, the success of the scheme is crucially dependent on the accurate classification of substances by suppliers. It is the R-phrases applied to a substance or preparation which determine its allocation to a hazard band and thus the intended target airborne concentration range. Therefore, a responsible approach to classification for all toxicological endpoints is a key factor for the scheme to be used successfully to recommend control strategies which should, as far as possible, be appropriate to ensure that the hazardous properties of a substance are not expressed.

Equally important and essential to the successful implementation of CB strategies is the effort to standardize the categorization of hazards, a primary objective of the global harmonization initiative discussed in a later section.

1.3.3 Occupational Control Considerations [Maidment 1998]

In writing about the development of the control predictive model, Maidment [1998] stressed the importance of limiting the number of factors in the model to control its complexity and applicability. The steps thus undertaken in developing the control predictive model are presented in Figure 3 [Maidment 1998].

1. Characterize CSs
2. Characterize exposure potential (physical factors of solids and liquids, operational factors)
3. Develop exposure predictive model
4. Establish relationship between exposure potential and hazard band
5. Substitute hazard band for exposure potential and invert model to produce control predictive model

Figure 3. Overview of approach used to develop control predictive model [Maidment 1998].

The details related to each step are described below.

1. CSs can be collapsed into four main categories (see Russell et al. [1998]): general ventilation, engineering containment, industrial closed systems, and special controls.
2. Characteristics of exposure potential can be summarized as those related to physical properties and those related to substance handling. With many parameters to consider, Maidment focused on the dustiness of solids and the volatility of liquids. The working group felt that three dustiness bands would adequately describe the properties of dusts and maintain the simplicity of the model: low, medium, and high. For liquids, the volatility of a liquid

would be captured by consulting a graph of boiling point versus operating temperature, separated into three regions: low, medium, and high. Operational factors were captured as the scale of the operation: small-, medium-, and large-scale.

3. The exposure prediction model was developed by combining bands for operational (quantity of use) and physical exposure potential. They found that all combinations could be collapsed into four bands each for solids and liquids, as described in Tables 7–8 below.

Table 7. Definitions of EPS* [Maidment 1998].

EPS	Description
EPS1	Gram quantities of medium/low dusty material
EPS2	Gram quantities of high dusty material; kilogram/tonne quantities of low dusty material
EPS3	Kilogram quantities of medium/high dusty materials
EPS4	Tonne quantities of medium/high dusty material

*Abbreviations: EPS=exposure predictor bands for solids.

Table 8. Definitions of EPL* [Maidment 1998].

EPL	Description
EPL1	ml quantities of low volatility material
EPL2	ml quantities of medium/high volatility material; m^3/liter quantities of low volatility material
EPL3	m^3 quantities of medium volatility material; liter quantities of medium/high volatility material
EPL4	m^3 quantities of high volatility material

*Abbreviations: EPL=exposure predictor bands for liquids; ml=millimeter(s); m^3=cubic meter(s).

4. The working group then integrated the EPS and EPL bands with the CSs 1–3 (previously shown in Figure 2, Section 1.3.1), producing Tables 9 and 10. These allocations were later "validated either by comparison with measured data or by wider peer review within the

British Occupational Hygiene Society (BOHS) and the British Institute of Occupational Hygienists (BIOH)," although these comparisons have not been published.

Table 9. Predicted dust-in-air exposure ranges (mg/m^3*) [Maidment 1998].

Engineering controls	Exposure Predictor Band			
	EPS*4	**EPS3**	**EPS2**	**EPS1**
CS1	>10	1–10	0.1–1	0.01–0.1
CS2	1–10	0.1–1	0.01–0.1	0.001–0.01
CS3	0.1–1	0.01–0.1	0.001–0.01	<0.001

*Abbreviations: CS=control strategy; EPS=exposure predictor bands for solids; mg/m^3=milligram(s) per liter.

Table 10. Predicted vapor-in-air exposure ranges (ppm*) [Maidment 1998].

Engineering controls	Exposure Predictor Band			
	EPL4	**EPL3**	**EPL2**	**EPL1**
CS1*	>500	50–500	5–50	<5
CS2	5–500	5–50	0.5–5	<0.5
CS3	0.5–5	0.5–5	0.05–0.5	<0.05

*Abbreviations: CS=control strategy; EPL=exposure predictor bands for liquids; ppm=parts per million.

As the highest concentrations listed are not recommended (i.e., >10 mg/ m^3 for dusts, 500 ppm vapors, which is near the highest HSE exposure limit of 1,000 ppm), the remaining five bands can be aligned with the five toxicological hazard bands, as shown in Table 11.

Table 11. Relationship between exposure and hazard band [Maidment 1998].

Exposure band—solid (mg/ m^3*)	Exposure band—liquid (ppm)	Hazard band
>10	>500	Not recommended
1–10	50–500	A
0.1–1	5–50	B
0.01–0.1	0.5–5	C
0.001–0.01	0.05–0.5	D
<0.001	<0.05	E

*Abbreviations: ppm=parts per million; mg/m^3=milligram(s) per liter.
See Brooke [1998] above for an explanation of allocation of R-phrases into the hazard bands and the validation of the hazard bands by comparison to 111 substances with OELs.

5. The final step was to invert the *exposure* predictive model to a *control* predictive model by replacing the exposure range in the exposure predictive model with the hazard band. This produces an empirical model that can be used to predict the appropriate CS to achieve adequate control based on the hazard and the exposure bands (Tables 12 and 13).

Table 12. Prediction of CS* from hazard band and exposure potential (solids) [Maidment 1998].

	Exposure Predictor			
Hazard Band	**EPS4**	**EPS3**	**EPS2**	**EPS1**
A	CS2	CS1	CS1	CS1
B	CS3	CS2	CS1	CS1
C	Special	CS3	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

*Abbreviations: CS=control strategy; EPS=exposure predictor bands for solids.

Table 13. Prediction of CS* from hazard band and exposure potential (liquids) [Maidment 1998].

Hazard Band	Exposure Predictor			
	EPL4	EPL3	EPL2	EPL1
A	CS2	CS1	CS1	CS1
B	CS2	CS2	CS1	CS1
C	CS3	CS3	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

*Abbreviations: CS=control strategy; EPL=exposure predictor bands for liquids.

In applying this approach for truly short exposures (i.e., <30 minutes), the CS could be dropped by one level (e.g., from CS2 to CS1).

With these three articles [Russell et al. 1998, Brooke 1998, Maidment 1998] the wider occupational safety and health community was thus introduced to the basics of the COSHH Essentials approach. While this strategy leans heavily on the work of historical models and approaches, it has a number of unique features, including an electronic version accessible via the internet. In addition, it theoretically meets all six of Money's [2003] core principles (understandability, availability, practicality, user-friendliness, confidence on the part of users, and transparent, consistent output). Despite its attributes, validation and verification remain important requirements. Oldershaw [2003] has cautioned that the COSHH Essentials approach could not be adopted uncritically by other countries; further, the approach must be considered as a component supplemental to personal protective equipment, training, health surveillance, and other elements of a comprehensive safety and health program.

While welcoming the move by HSE to provide guidance in the form of CGSs, Hudspith and Hay [1998] pointed out an additional obstacle to worker protection: communications barriers within companies. They recommended that HSE continues to stress the value of workforce involvement in safety and health issues.

1.3.4 Providing Control Guidance to Users

CGSs form a key component of COSHH Essentials. The number of CGSs continues to grow to address the need for practical and effective guidance on control for COSHH Essentials users, particularly those in SMEs. Solbase, a databank of control solutions for occupational hazards, shows potential as a source from which CGSs could be developed. With partners throughout Europe, Swuste et al. [2003, Swuste 2002] have tested Solbase, both for usability of the software and suitability of the recommendations yielded by Solbase, using 535 new and existing solutions (although currently most relate to manual or material handling, noise and vibration, machine guarding, and other safety issues, with few addressing air contaminants). The databank can be queried either by production process or by hazard.

1.4 Validation and Verification of CB Strategies

While CB strategies in general and COSHH Essentials in particular were easy to understand and implement, questions have been raised as to their accuracy. Researchers at the German German Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) examined the external validity of COSHH Essentials and found that in the majority of cases, it provided equal or greater worker protection compared to OELs; however, comparisons could only be made for a limited number of exposure scenarios. Researchers at the University of California–Berkeley who examined the International Labor Office (ILO) Chemical Control Toolkit had several concerns, including the margins of safety provided by the toolkit, particularly for vapors, assignment of R-phrases, and comparisons of air monitoring data with toolkit predictions.

Validation of all proposed CB strategies is essential for determining credibility. To date, however, only COSHH Essentials has been sufficiently developed and implemented to allow thorough evaluation and validation. Also receiving attention is the ILO (International) Chemical Control Toolkit, produced in collaboration with the UK HSE, International Occupational Hygiene Association (IOHA), and ILO, which is based on the UK HSE COSHH Essentials and is adapted for use worldwide [Jones and Nicas 2004, 2006a]. This version incorporates the Globally Harmonized System for Classification and Labeling (GHS).

According to Tischer et al. [2003a], three aspects of model evaluation can be applied to COSHH Essentials as follows:

1. Internal (conceptual) validation
    - Are the underlying assumptions plausible and consistent with established theories?
    - How uncertain are the model assumptions?
    - Are all relevant parameters considered?
    - Does the model reflect the relationship between the model parameters correctly?
    - Does the conceptual structure of the model reflect the structure of the real phenomenon?
2. External (performance) validation
    - Do the model estimates correspond to monitoring data or to the outcome of other models?
    - What is the accuracy and precision of the predictions?
3. Operational analysis
    - Is the model understandable by, and of practicable value to, the target group?

- Does the documentation meet the needs of the target group (language, skills, background knowledge)?
- How can it be ensured that the model is used correctly by the target group?

Brooke's work [1998] in comparing the R-phrases and resulting target airborne concentrations to the relevant health-based OELs on national lists (UK and German MAK) begins to address the first category on internal validation. The work of Tischer et al. [2003a], Maidment [1998], and Jones and Nicas [2004, 2006a,b] which are reported below, focuses on the middle category and begins to answer some of the questions regarding external (performance) validation. However, many questions still need to be answered in all three categories.

Kromhout [2002a] took strong exception to the lack of exposure monitoring in "generic risk assessment tools like COSHH essentials and expert systems like the Estimation and Assessment of Substances Exposure (EASE) . . . " as they ". . . are known to be inaccurate and they do not take into account the various components of variability in exposure levels . . . ." Kromhout built a strong case, estimating the variability in 8-hour shifts to be between 3,000- and 4,000-fold, and delineating the sources of variability as spatial, between workers and between groups. He argued that while providing exposure controls without having measured exposure concentrations would save money in the short term, in the long run it would be "penny wise but pound foolish." Topping [2002] responded that these arguments ignored the range of competencies in the workplace, and the number of firms handling chemicals. He stated that COSHH Essentials is not intended to replace monitoring, but rather to provide needed help to SMEs, pointing out that the cost of conducting the extensive monitoring suggested by Kromhout would be "astronomical" and that the capacity to do so does not exist. He allowed that the COSHH Essentials were designed to "err on the side of caution," that the strategy had been peer reviewed by BOHS experts, and that there had been no complaints about the recommended controls being too stringent. Kromhout [2002b] replied that he and the editor of *Annals of Occupational Hygiene* questioned the role of tools like COSHH Essentials in contributing to a "collapse of full time training of occupational hygiene professionals in Britain through lack of demand for expertise." Kromhout's strongest criticism was that EASE and COSHH Essentials had not been properly evaluated prior to release, and that peer review by BOHS experts could not replace the rigorous evaluation of testing for reproducibility and validity, with peer review of results in the scientific literature. He recommended that COSHH and EASE be used in the initial screening process.

1.4.1 HSE Studies [Maidment 1998]

According to Maidment [1998], the core model was validated by comparisons of Tables 9 and 10, with measured data, and by extensive peer review of the logic and content by experts. He noted that it was extremely difficult to find quality data for comparisons, and further, that the information describing control strategies often seemed to indicate that several control strategies were in use. Limited comparisons were described in his manuscript; heavy reliance was placed on peer review.

1.4.2 German BAuA Study [Tischer, et al. 2003a]

Tischer et al. [2002, 2003] at the BAuA conducted the first complete evaluation of the COSHH Essentials based on independent measurement data. The primary empirical basis for their analysis was measurement data collected within the preceding decade during BAuA field studies. Additional data were also provided by the chemical industry. These data are described in the following paragraph. Given that the data was not descriptive of all the possible exposure scenarios covered by the COSHH Essentials, the BAuA researcher were not able to evaluate the full range of the model.

BAuA data were obtained from their own laboratories, and all workplace measurements were conducted according to the German Technical Rules. Sampling durations were usually 1 to 4 hours, and were task-based (i.e., corresponding to a specific scenario). More than 95% were personal samples. Sources of uncertainty considered were volatility/dustiness, scale of use, and CS. For example, the uncertainty associated with volatility (of pure substances) was judged to be low, but quite complicated when mixtures were considered. Dustiness was considered to be a problem that requires additional attention. Scale of use was judged to be straightforward. (Most of the available data corresponded to the medium scale of use, with very little in the milliliter or tonne ranges.) Based on data available (i.e., 958 data points – 732 for liquids and 226 for solids), the researchers limited their analyses to scenarios in which the CS could be determined from the historical reports, assigning one of the four CSs.

Comparisons indicated that most of the measured exposures fell within the predicted ranges. Per Balsat et al. [2003], Tischer [2001b] found that the 95th percentile of data from different operations fit within the ranges predicted by the COSHH Essentials model. Exceptions were noted where some of the limited data points were above the predicted range: i.e., activities associated with carpentry workshops and application of adhesives, both of which represent small-scale, dispersive operations; and handling of powdery substances in kilogram quantities under local exhaust ventilation.

Tischer et al. [2003] noted that limited data, representing a limited number of possible combinations of Exposure Predictor Bands and CSs, were available for evaluation. In particular their data lacked description of scenarios involving the handling of milliliter or tonne quantities of low or high volatility/dustiness substances.

1.4.3 University of California—Berkeley Study [Jones and Nicas 2004, 2006a]

Jones and Nicas [2004, 2006a] reported less positive results in their evaluation of the ILO Chemical Control Toolkit, first presented at the 2nd International Control Banding Workshop (Cincinnati, OH, March 2004). The ILO Toolkit, as discussed above, was based on the COSHH Essentials strategy, but may not have been subject to the same periodic updates and revision. Their major objections fell into three categories:

1. Calculation of safety margins (No Observed Adverse Effect Level [NOAEL], or the Lowest Observed Adverse Effect Level [LOAEL], divided by the high air concentration of the hazard band) resulted in values of <100 for Hazard Groups B and C, and <250 for Hazard D for vapors. They noted that these values should be in the range of 1,000 to 10,000 for R48/20 *(Danger of serious damage to health by prolonged (inhalation) exposure)*, depending on whether the NOAEL or LOAEL was used as the basis of calculation.

   Jones and Nicas [2004, 2006a] made these calculations based on the generic COSHH criteria to avoid any errors caused by incorrect assignments of hazard bands. Brooke [1998] reported that some categories of materials were arbitrarily assigned to a higher hazard category based on their toxicity characteristics, and this would provide an extra factor of 10. Also, it must be pointed out that the Hazard Band values are generally in the same order of magnitude as

OELs (see Brooke [1998]) and also that it is not uncommon for acceptable risk levels of OELs to be in the range of 10^{-4} to 10^{-3}, in contrast to acceptable risk values in environmental settings of 10^{-6} to 10^{-5} [Jayjock et al 2000]. (For more detail on the in-house OEL setting process, see Naumann and Sargent [1997] and ABPI [1995].)

2. A comparison of the R-phrases (taken from the UK HSE "Approved Supply List" [National Chemical Emergency Centre at http://www.the-ncec/cselite]) assigned to commonly-used solvents indicated that the hazard group ratings assigned by the ILO Toolkit were lower than in the COSHH Essentials for 12 of 16 solvents. In five cases, the ILO Toolkit included an S notation (skin hazard) that was not on the R-phrases. Jones and Nicas [2004, 2006a] suggested that the authors of the ILO Toolkit should reconsider the hazard classification plan as the variations among CB strategies reduce confidence in the Toolkit among its users.
3. They compared reported air monitoring data and related use of ventilation systems, taken from NIOSH Health Hazard Evaluations (HHEs) for 31 vapor degreasing operations with 7 different solvents and 20 bag filling operations with 17 particulates. R-phrases for these liquids and dusts were obtained from the UK HSE National Chemical Emergency Web site (8 substances) and the Hazardous Substances Data Base (HSDB) of the U.S. National Library of Medicine (6 substances), and the Internet (9 substances). Volatility information was obtained from the HSDB, and dustiness and scale-of-use were obtained from NIOSH HHEs. Using this information, Jones and Nicas [2004, 2006a] determined the appropriate control approach and compared the actual measured exposures to the *maximum value* of the exposure band of the recommended exposure band.

This comparison resulted in two types of control errors: situations in which insufficient exposure control occurred in the presence of local exhaust ventilation (LEV) (under-control errors), and situations in which sufficient exposure control occurred in the absence of LEV (over-control errors). They found under-control errors in 96% of the 163 cases where LEV was present in vapor degreasing operations, and in 55% of the 49 cases where LEV was present in bag filling operations.

Their findings led them to multiple conclusions that may be summarized as follows relative to the CB process:

1. Recommended exposure bands do not provide consistent, or adequate, margins of safety [Jones and Nicas 2006b}.
2. The high rate of under-control errors highlights the need to evaluate the effectiveness of installed LEV systems using capture efficiency and/or air monitoring techniques.
3. The limited assignment of dustiness ratings to dusts complicates the process.
4. Specific guidance must be provided in cases where there is insufficient or inappropriate hazard information.
5. The R-phrase procedures criteria (specifically the use of minimum concentration values below which classification using the R-phrase values would not be applicable) are not compatible with U.S. regulatory practice.
6. Guidance about contacting professional assistance for engineering controls should be included on Task Guidance Sheets.

1.4.4 Expert Opinions on CB

Experts who have written about CB confirm its potential value as a risk assessment and management tool in the workplace, but express caution about the need for systematic, critical evaluation of the approach before widespread adoption.

1. According to Money [2003], "no systematic evaluation of the actual impact and effectiveness of the schemes has been undertaken . . . no systematic assessment has been undertaken of the impact that control banding approaches have had on the management of risk at the workplace or other levels. Thus, in terms of future developments in the area, it would appear that before further refinements are considered, there needs to be an extensive and systematic evaluation of the uptake and impact of a number of the key approaches."
2. Swuste et al. [2003] referenced Kromhout [2002b], stating that "The COSHH Essentials has met some criticism in the literature, focusing on the lack of a proper evaluation before its introduction into the occupational arena, as well as the generic nature of the tool, which will lacks [sic] precision and accuracy in situations where these are required."
3. Tischer et al. [2003a] have said that in the German occupational hygiene community, ". . . there was consensus that the scheme (COSHH Essentials) had great potential for further development. On the other hand, with respect to the exposure predictive model it has been argued that, due to its generic character, reliability and accuracy (safety) may have been sacrificed for the sake of simplicity and transparency. However, this assumption is not based on real measurement but reflects the low degree of confidence generally associated with generic models."
4. Oldershaw [2003] has cautioned that the COSHH Essentials approach cannot be adopted uncritically by other countries; further, the approach must be seen in the context of personal

protection, training, and health surveillance as elements of a comprehensive safety and health program.

These studies and expert comments presented in this section emphasize the need for collection of data under controlled scenarios to validate the predictions of the model. This validation must be seen as a separate activity from the verification of proper installation and maintenance of controls prescribed by a CB approach.

With regard to assessing the impressions about general usability of a CB model, a telephone survey of 500 purchasers of the paper version of COSHH Essentials revealed that 80% of the purchasers had used it, and only 5% had found it fairly difficult to use. Three-quarters had taken action, and 94% would recommend it to other businesses [Topping 2002b].

1.5 Specific Issues in CB

While COSHH Essentials is a valuable toolkit for protecting workers from airborne contaminants, in its original form it was limited to the inhalation route of exposure, and to certain chemicals used in manufacturing (others being regulated in specific statutes). Work is ongoing to expand applications to other topics, including dermal hazards, airborne crystalline silica, and asthmagens.

1.5.1 Dermal Absorption

A continuing concern within most CB strategies, including COSHH Essentials, is that they are primarily focused on the inhalation route of exposure. Garrod and Rajan-Sithamparanadarajah [2003] explored some of the issues involved in developing a dermal module in COSHH Essentials, and proposed alterations to the control approaches (levels 1–3). The current COSHH

Essentials model does not differentiate between substances that affect the skin (e.g., corrosives) and those that are absorbed through the skin as part of the exposure prediction step. This is possibly due to many chemicals being classified by the European system before extensive data were available to rank the risk of skin uptake. Other complicating factors include that some chemicals can act as carriers for poorly penetrating substances and that some risk phrases do not have exposure route indicators for systemic toxicity endpoints. Because of these limitations, Garrod and Rajan-Sithamparanadarajah suggested that most chemicals be considered as having the potential for skin uptake. In proposing three skin hazard bands (see Table 15), they considered the following questions:

1. Is there an identifiable dose threshold for the toxicological endpoint?
2. How serious is the health effect?
3. At what exposure levels do health effects occur?

Table 15. Skin hazard bands

Skin Hazard Bands	Included R-phrases*	Total daily skin burden of concern	Advice
1 – Lower skin hazard group	All R-phrases in COSHH Essentials hazard groups A, B, and C except R34 = causes burns R35 = causes severe burns R37 = respiratory tract irritation R43 = may cause sensitization by skin contact	Dust: 500 mg Liquid: 10 mg	Process: process modification, substitution of physical form Procedure: segregation, cleaning routines, training, hygiene procedures, laundry, skin care programs, PPE (disposable gloves), skin condition reporting

(Continued)

Table 15 (Continued). Skin hazard bands

Skin Hazard Bands	Included R-phrases*	Total daily skin burden of concern	Advice
2 – Higher skin hazard group	All R-phrases in hazard group D, plus R34, R35	Dust: 50 mg Liquid: 1 mg	Process: full containment (except small amounts of certain substances) Procedure: as above, plus controls, e.g., biological monitoring, permits to breath containment Advice: selecting gloves and other PPE, skin surveillance
3 – Highest skin hazard group	All R-phrases in hazard group E, plus R43	Any amount of dust or liquid	Seek specialist advice.

*Abbreviations: COSHH=Control of Substances Hazardous to Health; mg=milligram(s); R-phrases=Risk Phrases; Adapted from Garrod, Rajan-Sithamparanadarajah et al. [2004].

Thus, most of the chemicals in COSHH Essentials hazard groups A, B, and C are considered in the lower skin hazard band. Compared with the inhalation hazard rankings of chemicals, those that cause burns (R34), severe burns (R35), and skin sensitizers (R43) are moved to higher hazard groups.

Regarding dermal exposure, Garrod and Rajan-Sithamparanadarajah [2004] presented a strong case against considering duration of exposure as a factor influencing uptake, as the skin can act as a reservoir, and thus contribute to uptake of contaminants even after exposure has ceased. Additional arguments for this position include documented penetration and retention of contaminants by gloves, contamination of the inside of gloves the second time they are put on, and inevitable dermal contamination when working outside containment. They allowed for the possibility of two durations when considering exposure banding: a single splash that is immediately removed and all other scenarios. These authors concluded that dermal exposure cannot currently be banded in the way that inhalation exposures are banded. They offered recommendations for altering COSHH Essentials to account for dermal exposures, including guidance for breaching containment or use of certain hazardous chemicals, raising the control approach in certain cases, disallowing any reductions in control approach based on short-term usage, use of skin surveillance when skin sensitizers are used more often than once per month, and consideration of the concentration of liquid mixtures and of the specific body area in contact with chemicals.

Skin exposure to occupational hazards is a pervasive challenge in many industries. Since the level of control cannot be quantified as increasing levels of 10-fold protection (as can be done with inhalation exposure control), biological monitoring has been recommended to assess adequacy of control. In summary, Garrod and Rajan-Sithamparanadarajah [2004] stated that

> . . . hazard banding is feasible, exposure banding is not, and control banding for skin cannot at present be done with any rigour *[sic]*, but it is feasible to provide suitable control guidance sheets for dermal exposure control.

The challenge for application of CB for dermal hazards lies in the banding of dermal exposures. Much research has been devoted in recent years to developing methodologies for risk assessment of dermal contact with chemicals, with the focus on dermal exposure assessment. The Dermal Exposure Assessment Method (DREAM—a method for semi-quantitative dermal exposure assessment) [Van-Wendel-de-Joode, Brouwer et al. 2003] is a systematic and structured approach for dermal exposure assessment; however, in its present form, it is highly complex. In

DREAM, the model's 33 exposure determinants were mostly assigned by educated assumptions; it is time-consuming to conduct, and requires an occupational health professional to complete a questionnaire for model inputs.

The aim of RISKOFDERM, an EU-funded project, is to develop a validated predictive model for occupational dermal exposure assessment that could be adapted into a practical dermal exposure toolkit for SMEs [EC 2004; van Hemmen et al. 2003; Marquart et al. 2003; Goede et al. 2003; Warren et al. 2003; Oppl et al. 2003; Schuhmacher-Wolz et al. 2003]. The RISKOFDERM toolkit became available on the Internet in March 2004 with the intent to be understandable and user-friendly. RISKORDERM was also intended to raise awareness, estimate exposures, identify control actions, recognize hazard potential, and recommend control actions in hierarchical order [van Hemmen et al. 2003]. The toolkit was evaluated by a panel of international industrial hygienists and revised according to findings of then on-going RISKOFDERM research. Both paper and electronic formats are available online, which are now available for use by educated nonexperts, who would ask fairly simple questions and be guided to qualitative scales for dermal exposure, resulting risk, and possible control measures. As this project includes several key persons from the UK HSE, the outcome of RISKOFDERM may very well support a relatively simple dermal exposure banding concept that could be incorporated into COSHH Essentials or other toolkits that are in the development process.

1.5.2 Silica (UK HSE)

The HSE has developed control guidance sheets for silica—Silica Essentials. These sheets are part of a new phase of COSHH Essentials where the guidance is task specific and targeted at specific industry sectors, such as foundries, construction, quarries, brick making, and ceramics.

They were launched on the Internet in 2006 and provide practical standards that industry can apply to reduce exposure to silica. Silica Essentials is a good example of the applications of the CB strategy where direct advice can be given, based on good control practice recommendations of industry experts. They require no detailed data input from the user and do not rely on R-phrases. The appropriate guidance sheets can be determined by identifying the appropriate activity for which guidance is sought, such as rock drilling, fettling castings, tile pressing, or abrasive blasting. The work to develop the CGSs is complementary to other initiatives from HSE to raise awareness of industry hazards and the importance of adequate control to reduce ill health. Such initiatives on silica include the silica information sheets and an approach to control exposure to silica dust in small potteries.

1.5.3 Asthmagens (UK HSE, NIOSH, OSHA)

In the United Kingdom, an estimated 1,500 to 3,000 new cases of occupational asthma occur each year. This rises to 7,000 cases a year if asthma made worse by work (work-related asthma) is included. In the United States, it is estimated that occupational asthma incidences range from 6.3 to 44.1 per 100,000 [Henneberger et al. 1999], and task-related exposures associated with occupational asthma are considered to be an appropriate focus for preventive strategies [Wagner and Wegman 1998]. In 2003, HSE included in their Strategic Outlook the intention to build collaborations with international technical and scientific organizations such as NIOSH. This collaborative HSE and NIOSH work includes a focus on asthmagens in relation to its inclusion within CB strategies. Although no conclusive CGSs are currently available relating to this cooperative research, this approach is an example of international organizations' belief that the CB strategy is worthy of consideration for addressing occupational exposures in the workplace. Efforts to promote collaboration are currently underway, including development of a letter of agreement among HSE, NIOSH, OSHA, and BAuA to explore CB and the joint creation of hazard guidance materials.

1.5.4 Asbestos Essentials (UK HSE)

Another UK HSE product is a manual entitled *Asbestos Essentials: Task guidance sheets for the building maintenance and allied trades*. This guidance manual [HSE 2001] includes eight "Equipment and Method Guidance Sheets" on topics such as training, building enclosures, use of a Type H vacuum cleaner, and wet methods. R-phrases are not included; rather, the guidance is presented by task. The 25 Task Guidance Sheets (TGSs) cover tasks such as removal of gaskets and floor tiles, and painting insulating board. Each TGS is structured according to description of task, PPE, preparing the work area, repair, cleaning, personal decontamination, and clearance procedures.

1.5.5 Variations of the Model

Users of CB strategies quickly realized that one strategy would not fit all needs. Variations have been developed by several nations (including France, Germany, Belgium, The Netherlands, and Singapore) and multinational corporations.

Interest in CB strategies on the part of the European occupational hygiene community were spurred by the introduction of the Chemical Agents Directive [1998; Money 2003; EC 1998]. Several approaches have resulted [Money 2003]. The French approach [UIC 1999] evaluates the probable effectiveness of risk management in protecting workers at the company level. It suggests appropriate references to provide guidance based on the type of substance and handling procedures. The following references and related activities are specifically noted for their impact on chemical risk management:

4. REACH would shift the burden of proof of chemical safety to industry and would apply to most chemicals in commerce [EC 2001].
5. The European Chemical Industry Council (CEFIC) exposure management system (CEMAS) [Money 2001a] provides a guidance tool for SMEs, to collect workplace exposure data that can be coupled with hazard information and deliver advice on risks and risk management, recommending whether exposure monitoring should be conducted. (See Figure 6 from Money [2003].)
6. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) tiered and targeted risk assessment [ECETOC 2002] could aid in the registration of a large number of chemicals under REACH. This is a streamlined approach that applies CB concepts in a tiered manner. (See Figure 7 [Money 2003].) Tier 0 screens out chemicals not presenting an immediate risk to humans or the environment. Tier 1 identifies uses of a chemical that may present further risks to be investigated in greater depth in Tier 2. In Tier 1, margins of exposure (MoE) are compared with generic OELs for the chemical's hazard category while Tier 2 assessments are conducted in accordance with EU risk assessment principles.

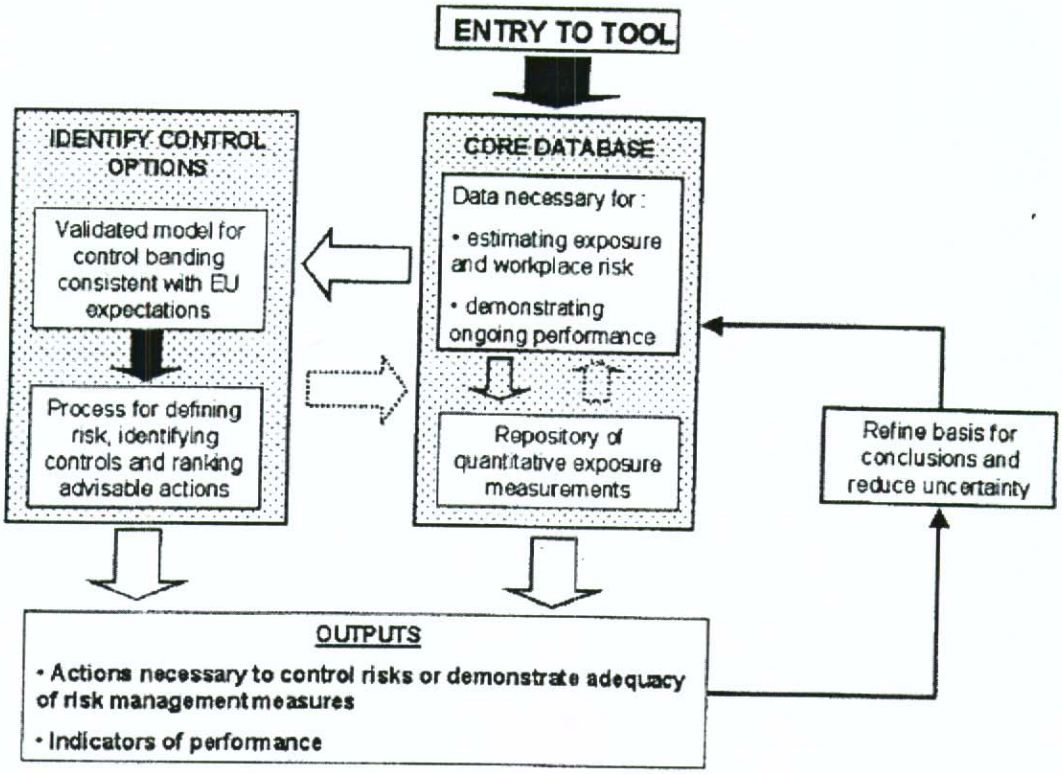

Figure 6. The CEFIC exposure management system (CEMAS).
[Reproduced from: Money CD [2003]. European experiences in the development of approaches for the successful control of workplace health risks. Ann Occup Hyg *47*(7):533–540, with permission from Oxford University Press, British Occupational Hygiene Society, and C.D. Money.]

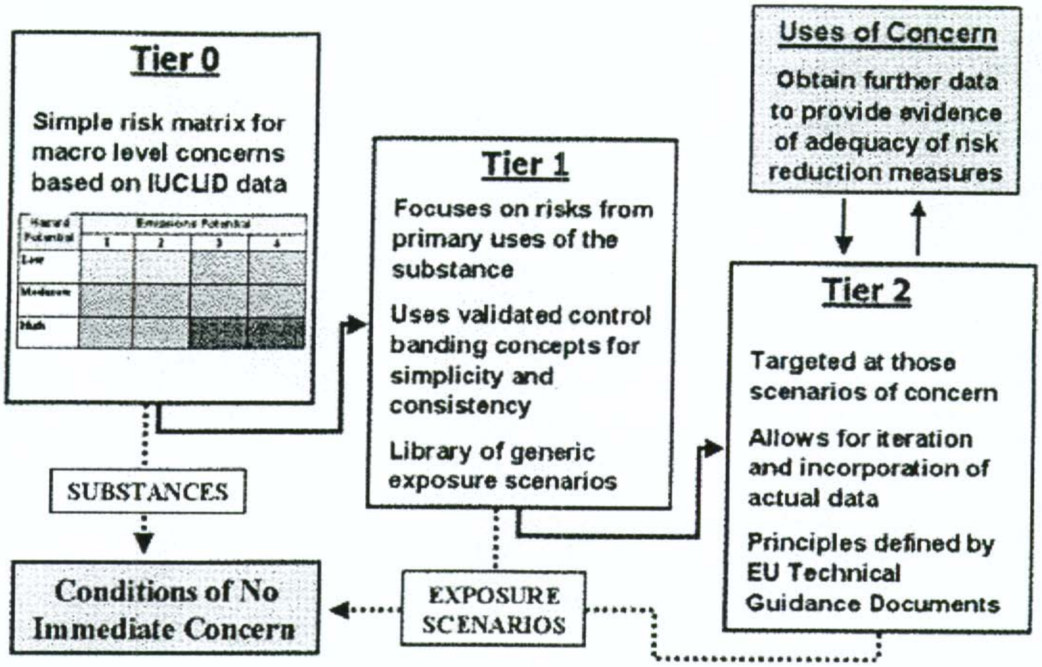

Figure 7. Key elements of the ECETOC approach for the tiered and targeted risk assessment of chemicals.

[Reproduced from: Money CD [2003]. European experiences in the development of approaches for the successful control of workplace health risks. Ann Occup Hyg *47*(7):533–540, with permission from Oxford University Press, British Occupational Hygiene Society, and C.D. Money.]

1.6. CB Strategies Used in Countries Other Than the UK

1.6.1 France

Vincent and Bonthoux [2000] of the Institut National de Recherche et de Sécurité (INRS) research center in France reported on a system to prioritize risk assessment of chemicals at the company level using simple and available information. It considers hazard and exposure factors (translated from French):

> This risk results from the conjunction of a hazard and an exposure. In the case of a chemical product, the risk corresponds to the toxicological properties of the product; the exposure is linked to a number of factors such as the quantity used, the conditions of use, the physical characteristics of the product, the means of prevention utilized, and the duration of exposure.

Based on information derived from safety data sheets and labels, chemicals are assigned to categories based on (1) hazard classification and labeling (I to V), (2) frequency of use (I through IV), and (3) quantity used (I through V). Quantity and frequency of use scores are combined to create a classification by potential exposure (I through V, based on expert opinion). The scores for hazard (D) and potential exposure (E) are combined based on the following equation:

Product score = $10^{(D-1)} \times 3.16^{(E-1)}$

The resulting scores have been ranked by experts into three priority classifications (A=elevated, B=middle, and C=weak) that can be used at the plant level to prioritize chemical substances for further risk assessment. Internal validation of the model indicated in overestimation 19% of the cases, and underestimation in only 1%. The authors concluded that another method of evaluation of the real risks at the workplace would be developed to complement this method.

1.6.2 Germany

Germany is the third largest chemical producing nation in the world, and the largest chemical exporting nation [Adelmann 2001]. As such, it has taken measures to assist in management of chemicals in developing countries: to support developing countries in implementing the

Rotterdam (prior-informed-consent [PIC]) and Stockholm (Persistent Organic Pollutants [POPs]) Conventions, to build capacity, and to conduct demonstration projects [Tischer 2002; Tischer and Scholaen 2003b; Scholaen 2003]. Under its Convention Project on Chemical Safety the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) has developed a Chemical Management Program Guide as part of its Pilot Project on Chemical Safety. The Chemical Management Guide is a method to demonstrate and document how chemical safety in developing countries and small businesses can be improved and sustainability implemented in line with international standards. Its use has been implemented at international sites in Argentina, Indonesia, and EU countries. The GTZ chemical management guide and pilot project on chemical safety is a unique program developed specifically to meet the needs of small businesses and developing countries for addressing chemical hazards.

The teaching methodology developed by the GTZ is based on long-term experience from the initiation of workshops in developing countries that included multiple day training sessions supported by technical information from the BAuA [Scholaen 2004]. This training is presented in a participatory fashion that involves workers with the company managers and health, safety, and environmental professionals in order to complete a facility chemical plan together in a manner that supports the participatory action research approach [Zalk 2002]. The guiding principles of the Chemical Management Guide include the practice of sound management of chemicals, reduction of company production costs, increase in product quality, and ultimately reducing the risk to worker health, and environmental protection. The first of three steps is to identify *hot spots* in a company's manufacturing processes, e.g., places where inefficient storage, handling, use, and disposal can be observed. Preparation of a detailed chemical inventory is the second step. Use of one or more of multiple tools comprises the last step: basic risk assessment, description of control approaches, use of material safety data sheets (MSDSs), safety phrases for hazardous substances, and symbols for labeling hazardous substances. This approach has been successfully ground-tested in Indonesia. While CB may be too sophisticated for many small enterprises, field observations suggest that since the medium and larger enterprises have more MSDSs on site, they have a greater potential for conducting risk assessments using the ILO Toolkit [Tischer and Scholaen 2003b].

Additional work in Germany relates to the GHS. A guideline to assist implementation of the chemical directive 98/24/EEC has been elaborated by a contractor of the Commission and has been reviewed by an ad hoc working group on chemicals of the tripartheid advisory board to German employment. In the annex of this guideline the COSHH Essentials have been included. This guideline is a recommendation to member states for implementation of 98/24/EEC and is not mandatory. It is a decision of countries to use it. At present the guideline await its final approval by the advisory body and then will be published.

1.6.3 The Netherlands (Stoffenmanager)

Stoffenmanager, a web-based tool for SMEs for working safely with chemical substances, factors exposure potential into its model through the use of an interactive chemical risk management approach. It was developed by The Netherlands to assist SMEs in assessing and controlling risks associated with hazardous substances. Developed by ArboUnie and TNO Chemistry, a Dutch contract research organization, under a grant from the Dutch Ministry of Social Affairs and Employability, this tool was constructed by using "parts of methods from Germany, Austria, the United Kingdom, Sweden, and Finland" [Tijssen, et.al. 2004]. In addition, information gleaned from expert IH workshops was incorporated into the tool's development.

Stoffenmanager supports the inventory of the hazardous substances, assessing and controlling risks in a risk inventory, obtaining a plan for control measures, making instruction sheets for the workplace, and helping in storage according to guidelines. For the risk inventory, the employer uses R-phrases categorized according to COSHH Essentials. Then the employer completes a qualitative exposure assessment by responding to seven questions to determine the chemical's exposure class. The tool automatically calculates a risk score to complete the initial assessment of the health risk. Based on the risk score, the employer can review the selection of various control measures and choose the most appropriate and effective one accordingly [Tijssen et.al. 2004]. Stoffenmanager is currently generic but the Dutch have plans to adapt it to fit into various industry sectors at a later date. Industry sector-specific tools would be very helpful and enhance its use [Tijssen et.al. 2004]. (See Section 1.2.5.)

1.6.4 Norway (KjemiRisk)

Developed through the cooperation of corporations within the Norwegian oil industry, KjemiRisk is an assessment of chemical health risk based on experience and practice in these industries. The tool takes the following into account: physical properties of the chemical, the handling of the chemical and the appropriateness of the technical, organizational, and personal barriers established to control the chemical exposure, and the duration and frequency of the work task using R- and S-phrases as its basis. Chemicals are grouped into one of five health hazard categories based on R- and S-phrases. As part of the KjemiRisk application, 15 common tasks are defined, and the handling of the chemical, its physical state, duration and frequency of use, potential for exposure, and the appropriateness of controls in place are used in the conceptual model. The risk assessment is divided into two phases that include the potential risk and the final risk. These are adjusted based on consideration of the reliability and appropriateness of the established controls. The risk assessment provides an evaluation of task-based work procedures which have the potential to cause illness related to lungs, internal organs, and skin [Smedbold 2004]. KjemiRisk can be considered both a rough risk assessment tool when used by line managers or safety and health generalists and an expert tool when used by industrial hygienists. It is currently available in Norwegian and English as an individual or a network application when integrated with an appropriate server. Expansion of web applications, improvement of reporting functionalities, and substitution of capabilities are currently being considered for development.

1.6.5 Belgium (Regetox)

A two-stage risk assessment strategy (Regetox) was developed and tested in Belgium [Balsat et al. 2002a,b; 2003] in response to the European Chemical Agents Directive 98/24/EC (April 1998), which requires companies to assess and manage chemical risks in the workplace. In order to minimize the number of chemicals (and resulting costs) for which risk assessment must be conducted, the first stage of the strategy uses the French (INRS) ranking of potential risk based on R-phrase, annual quantity in use, and frequency of use, as described above in Section 1.6.1 [Vincent and Bonthoux 2000]. Only products receiving a rating of medium or high are carried forward to the second stage, which uses COSHH Essentials. When mixtures are being used, the risks are evaluated for each harmful component according to the composition by weight of the mixture. For cases in which contaminants are generated during the process, e.g., aerosols generated during spray painting, the EASE model is used. Feasibility studies conducted in two firms revealed lacking or inadequate MSDSs. There was only one case in the two companies in which the strategy failed to reveal need for improvement in the work situation. The authors felt that simple examination of the work situation would have indicated the need for semi-quantitative risk assessment. Further lessons drawn from the trial are that most companies are not prepared to comply with the European Chemical Agents Directive and that the use of the Regetox approach can be helpful to companies, but requires training of prevention advisors and a strategy to involve employers, staff members, and workers to assist in collecting basic information for the risk assessment.

1.6.6 Singapore (SQRA)

The Semi-Quantitative Risk Assessment (SQRA) was developed in Singapore by the Ministry of Manpower (MOM). The purpose of the SQRA is to facilitate identification of chemical hazards, evaluation and potential for exposure, risk level determination, and prioritization of appropriate controls to address the identified risks. As the foundation for the SQRA, three methods are recognized for exposure evaluation: personal exposure monitoring, selection of exposure factors and parameters, and applying empirical and theoretical formulas to estimate exposures at the plant or process design stage. The International Chemical Control Toolkit (ICCT), based on COSHH Essentials, was tested in parallel with applications of the SQRA to evaluate their utility and to perform comparisons based on theoretical and empirical aspects [Yap 2004]. Direct comparison of the two approaches can be stratified by their respective control approaches based on risk levels. The ICCT first control approach (general ventilation) fits with SQRA risk level 1 (negligible risk) and level 2 (low risk), suggesting periodic re-assessment and personal air monitoring requirements. The ICCT second engineering control approach aligns with the SQRA level 3 (medium risk), indicating a need to implement and maintain controls, review the assessment every 3 years, and determine if training and personal air monitoring are necessary. The third control approach for the ICCT (containment) is comparable to the SQRA level 4 (high risk), suggesting implementation of engineering controls, personal air monitoring and training, PPE requirements, and reassessment of risk after all controls are put into place. The ICCT fourth control approach (special circumstances) aligns with the SQRA level 5 (very high risk), directing users to consult specialists for advice, and comply with requirements for risk level 4, including a reassessment after controls are implemented.

In the theoretical comparison of the CB strategies, the risk level is derived from exposure factor calculations that consider vapor pressure or particle size, the ratio of the odor threshold to the applicable OEL, the amount of chemical used and duration of work per week, and the hazard control measures. This result is then compared with the control approach determined by the ICCT, giving a direct evaluation of the consistency of the models as the ICCT does not take into account existing hazard control measures. The empirical comparison of the models uses actual personal air monitoring data used to derive the SQRA method's risk level to assess against the Toolkit's control approach. This comparison was performed on 27 selected SME processes including metal working, paint manufacturing, chemical processing, printing, dry cleaning, and electronics industries. The results of the theoretical comparison indicate that the Toolkit and the SQRA method are somewhat consistent with a difference between the control approach and risk level being one to two bands. In the majority of cases using the empirical comparison, it was determined that the ICCT estimates a higher risk than the SQRA, thereby suggesting a higher level of control [Yap 2004].

1.7 Recent Events Surrounding CB

CB is currently the subject of much interest, both nationally and internationally. International workshops have been held in London (2002), Cincinnati (2004), and concurrently in Pilanesburg, South Africa and Orlando (2005). International collaborative agreements have been forged to coordinate the work of international agencies and their partners, and a global implementation strategy has been developed.

1.7.1 First International CB (ICBW1)

ICBW1 was held in London, on November 4–5, 2002, with the sponsorship of BOHS, BIOH, UK HSE, IOHA, the World Health Organization (WHO), and the ILO. In addition to providing a clear description of the CB process, Jackson [2002] and Jackson and Vicker [2003] noted the following:

- The UK HSE, IOHA, and ILO have collaborated to produce the Chemical Control Toolkit (or ICCT), which was based on the UK HSE COSHH Essentials, adapted for use internationally. This version incorporates the GHS.
- Any version of the CB approach must be simple to use and compatible with existing work methods.
- Adapted versions range from the sophisticated approaches pioneered by the pharmaceutical industry, to the holistic GTZ approach (Chemical Management Guide) [Adelmann 2001]. The GTZ approach has been marketed to employers, e.g., in Indonesia, on the premise that the control of chemicals reduces waste and loss in addition to protecting worker health and environmental quality.
- While valuable in a large variety of workplaces, the wide range in versions of CB is necessary for broad application. In particular, two types of approaches may be necessary:

one for small businesses in mostly developed countries and another for developing countries.

- The role of the International Programme on Chemical Safety (IPCS) International Chemical Safety Cards (ICSC) in providing relevant information was acknowledged, with the possibility of these cards being updated to include the necessary data, e.g., GHS, to support CB being considered.

A strategic planning meeting held during the workshop was attended by representatives from a number of national and international organizations. It was agreed that a (now named) International Technical Group (ITG) on CB would be organized, with the IPCS serving as secretariat. The major purposes of the ITG are to share the knowledge gained from trials and demonstration projects, maintain the integrity of the ICCT, and ensure that the technical aspects of the system are maintained and updated, e.g., to reflect changing national legislation and implementation of the GHS. (See Appendix C for the ITG's Global Implementation Strategy. Also, see Zalk [2002b].)

Most of the presentations from this workshop have been reviewed elsewhere in this document; see Fairhurst [2002], Gardiner [2002], and Oldershaw [2002]. All of the presentations from ICBW1 can be viewed at http://www.bohs.org/mod.php?mod=fileman&op=view_cat&id=14.

1.7.2 Second International CB Workshop (ICBW2)

The ICBW2, subtitled *Validation & Effectiveness of Control Banding* (March 1–2, 2004, Cincinnati, OH) was organized by eight partners [Nelson and Zalk 2004a, Nelson 2004]:

- ACGIH
- American Industrial Hygiene Association (AIHA)
- ILO
- IOHA
- NIOSH
- U.S. National Safety Council (NSC)
- OSHA
- WHO

Dr. John Howard, the Director of NIOSH, opened the workshop on the first day, and Mr. John Henshaw, Assistant Secretary of Labor, OSHA, led off on the second day. Twenty-two speakers from Europe, the United States, Asia, and South America shared their research and experiences on topics ranging from the birth of CB concepts in the pharmaceutical industry, to adaptation of the concept to meet national needs in several developed and developing countries, to qualitative and quantitative validation studies, to new and innovative applications of CB in fields such as ergonomics. The workshop entailed 1½ days of platform sessions and an integrated poster session covering a broad range of CB topics including validation and effectiveness applications, collaborative efforts, new international approaches, expansion of range, and case studies. Following the platform and poster sessions, the 165 participants, who represented 13 countries, participated in five interactive breakout sessions:

- Scientific Session I: The Research Agenda for Developing Nations
- Scientific Session II: The Research Agenda for Developed Nations
- Expanding the Range of CB

- Performance-Based Exposure Control Guidelines
- Open Topics

Breakout sessions recorded participant viewpoints regarding the greatest challenges currently facing CB. Priority issues included cost-effectiveness and efficiency to expand the reach of CB concepts while minding the largely volunteer effort bringing this forward. For example, comparing the relative priority of applications in the evolved and well-funded pharmaceutical industry to that of approximately 90% of the world's workforce in developing countries with no foreseeable budget for preventive approaches and occupational safety and health resources is difficult. Presentations and discussions of CB topics covered the multiple tools and CB strategies for consideration. Most of the presentations from the ICBW2 can be viewed at http://www.acgih.org/events/course/controlbandwkshp.htm.

Significant outcomes of ICBW2 were the framework for a research agenda for developed and developing countries, the creation of a National Control Banding Workshop (NCBW) Organizing Committee, and a consensus Global Implementation Strategy from the ITG on CB. The CB ITG, led by WHO IPCS and ILO, had the opportunity to meet before, during, and after ICBW2 to finalize the Global Implementation Strategy for release after the event. The complete implementation plan is contained in Appendix C of this document. The NCBW was held in March 2005 in Washington D.C., to review an early draft which became the foundation of this document, and to discuss consideration of U.S. strategies to employ CB concepts.

1.7.3 International Agreements

ILO and WHO agreed to work together under the auspices of the IPCS on January 23, 2003. The roles of each organization were spelled out in the agreement [Vickers and Fingerhut 2002].

An agreement on the Global Implementation Strategy for the Occupational Risk Management Toolbox was outlined by the ITG at the 2ICBW discussed above, and approved on May 28, 2004. This strategy, which discusses partners, stakeholders, the ICCT, key elements, terms of reference, and the international research agenda, can be found in Appendix C.

2 CRITICAL ANALYSIS OF CB STRATEGIES

Strengths and weakness of CB strategies center around the differences between CB and COSHH Essentials, differences between quantitative and semi-quantitative approaches, impacts on practicing industrial hygienists, role of OELs, exposure assessment versus exposure control, predicting and controlling exposures, and validation and maintenance of implemented controls.

2.1 Evaluating CB Efforts

In evaluating the weaknesses and strengths of the CB strategy, it is useful to refer to an outline of common issues (Table 16) that are more fully addressed in the following sections.

2.1.1 Direct Comparison of Strengths and Weaknesses of the CB Strategy

2.1.1.1 Overall Weaknesses. To many IH professionals the CB strategy is perceived as synonymous with the COSHH Essentials. This misunderstanding is an important reason that a portion of the profession is critical of the CB concept. This is not to say they are critical of the COSHH Essentials specifically, rather that this Toolkit is all that CB is and all it has to offer. This criticism has value in that it has stimulated discussion of many potential weaknesses of the CB strategy, even if the premise for the criticism may be misconceived [Oldershaw 2003; Tischer et al. 2003a].

Table 16. Issues relating to the strengths and weaknesses of the CB* strategy

CB Strategy Issues	Weakness Summary	Strength Summary
Perception of CB Being the same as the COSHH Essentials	Highlighting COSHH Essentials within CB presentations led to misunderstanding that they are the same. Research critical of COSHH is therefore critical of CB.	Current CB publications and events are clarifying that CB is an overarching strategy and not a single toolkit. COSHH Essentials critique led to improved revisions.
Replacing Good Science with Vague Controls	As IH practice in the United States is based on solid scientific protocols, why replace them with potentially under- protective CB outcomes?	Traditional IH practice is expensive, and options are necessary to protect most U.S. workers. CB strategies reduce costs, and promote IH expertise as needed.
Affecting Professional Industrial Hygienists	Implementation of CB strategies will reduce the need for IH consultants and move profession toward ES&H generalists.	CB strategy indicates thresholds that require IH expertise. With CB implementation employers will be educated about IH concepts and practices.
CB Will Replace OELs	Some professionals believe that moving CB forward in the absence of OELs will strengthen the argument to eliminate them.	CB strategies will not serve as a replacement for OELs in the United States. CB validation protocol will include personal monitoring for OEL use.
Exposure Assessment versus Exposure Control	Traditional exposure assessment relies heavily on personal IH monitoring. Some perceive CB as eliminating this crucial step.	CB requires IH personal monitoring for validation and maintenance. Task-based control solutions are appropriate given sufficient historical data.
Predicting Exposures and Implementing Controls	COSHH Essential's interim step of predicting exposures is an area estimate, offering controls in the absence of workplace variations.	COSHH Essentials criticisms are assisting in perfecting the model. Task-based point source models do not require exposure prediction.
Validation and Maintenance of Implemented Controls	Current CB strategies implement static controls. Validation needs to include dynamic aspects of initial accuracy, process change, and control degradation.	CB validation protocol will include evaluating dynamic implementation strategies. The database resulting from this process will offer a useful task-based CB solutions database.

*Abbreviations: CB=control banding; COSHH=Control of Substances Hazardous to Health; ES&H=Environmental Safety and Health; OEL=occupational exposure limit.

2.1.1.2 Overall Strengths. The CB Strategy provides an additional approach for protecting workers' safety and health, building upon and supplemental to traditional strategies. A strength of the CB strategy is its evolutionary timing in relation to the electronic age of communication. The basis for CB is not a new concept revolutionizing the IH profession. In many aspects it provides the opportunity to utilize historical field research for work-related exposure analysis and assessment, and related controls and solutions when available. Electronic communication offers an opportunity to organize and disseminate this information broadly, effectively, and directly to the intended audience in a manner previously unattainable. Much of the control information necessary for developing CB strategies is derived from work previously developed for workplace exposure solutions by scientific and technical organizations around the world. The work set forth by IOHA, WHO, and ILO has initiated a process to streamline available exposure control information and make it available in an appropriate form to address workplace hazards. This work is complemented by the NIOSH Research to Practice (r2p) initiative (described at http://www.cdc.gov/niosh/r2p/) which is focused on the transfer and translation of research findings, technologies, and information into highly effective prevention practices and products that are adopted in the workplace. Fitting well with the CB strategy, the goal of the NIOSH r2p initiative is to reduce illness and injury by increasing technology transfer and workplace use of effective research-tested solutions. In order to achieve this, NIOSH is continuing to work with its partners to focus research on ways to develop effective products, translate research findings into practice, target dissemination efforts, and evaluate and demonstrate the effectiveness of these efforts in improving worker safety and health. With similar efforts in place in various countries around the world, the CB strategy has utilized capabilities of electronic communication both in its development and its dissemination.

Another way to view CB is as a potentially powerful tool for knowledge management. Knowledge management is an emerging field focusing on assessing the creation, transfer, and use of knowledge to address specific challenges [Schulte et al. 2004]. The development of hazard control guidance materials and the application of CB strategies provide a means for effective knowledge management. Generally, knowledge management has described efforts within and between companies to consider knowledge as a manageable asset. Occupational safety and health knowledge can be considered a manageable asset by businesses. How knowledge is stored, transferred, and used has not been well characterized in the occupational safety and health field in general. However, extensive resources in other disciplines exist including information theory, health communications, social marketing, diffusion of innovations, sociology of knowledge, and individual and organizational behavior that could be applied. Using techniques from these areas to conduct research and disseminate knowledge could advance knowledge management in the field of occupational hygiene. Additional benefits would derive from efforts to engage specialists from those fields in collaborative projects to apply theories and research to occupational safety and health questions.

2.1.2 Perception of CB Being the Same as COSHH Essentials

2.1.2.1 Weakness. As the most complete chemical-related Toolkit available, the COSHH Essentials is an example of how a control banding strategy can be effectively implemented. A common misperception, however, is that CB and COSHH Essentials are identical. Because COSHH Essentials are viewed as pioneering, they were also widely scrutinized as the primary mechanism for applying control banding. Consequently, some confusion stems from the misunderstanding that the nature of COSHH Essentials is to use refined parameters to offer a best estimate of personal exposures. To practicing industrial hygienists in the United States this could be viewed as an unnecessary step since their job is to measure and characterize personal exposures; therefore, the estimation of personal exposures within a toolkit is inappropriate in concept because it does not require use of IH sampling equipment or the expertise of the industrial hygienist in its analysis and application. COSHH Essentials has met criticism in the literature for the generic nature of the tool that does not adequately or accurately take into account the environment and parameters within which the exposure occurs [Swuste et al. 2003; Harrison and Sepai 2000]. Another criticism is that the COSHH Essentials generic approach is too simplistic when accuracy and evaluation should be considered essential [Money 2003; Swuste et al. 2003; Tischer et al. 2003a; Kromhout 2002b]. Taken holistically, it may serve as an underestimate of exposure potential due to skin adsorption, inappropriate PPE selection or use, concentration of exposures within a constrained work environment, proximity of the worker to the exposure source, or the many related complicating factors that the professional industrial hygienist is trained to observe and consider when recommending controls and solutions for a specific worker and workplace [Guest 1998; Tischer et al. 2003a; Jones and Nicas 2004, 2006a,b; Brooke 1998; Loughney and Harrison 1998; Palmer and Freegard 1996]. In such a case, use of COSHH Essentials may indicate that a manufacturing operation is safe when parameters not considered may actually result in potentially hazardous exposures [Jones and Nicas 2004, 2006a,b; Russell et al. 1998]. Consequently, it is the job of a field industrial hygienist to recognize this potential.

2.1.2.2 Strength. Since the COSHH Essentials were first developed, it has been revised to improve its ease of use, accessibility, and transparency to the average nontechnical manager [Balsat et al. 2003; Oldershaw 2003]. The COSHH Essentials framework and control recommendations have also been compared to data in established exposure databases [Balsat et al. 2003; Tischer et al. 2003a; Jones and Nicas 2004, 2006a,b]. The example of COSHH Essentials has also served as a template for the entire CB strategy. Attempts to publicize, educate, and train IH professionals on this concept have been intricately interwoven with an intensive effort to seek out the weaknesses of its foundation [Oldershaw 2003]. This approach is heightened in the United States as the full range of the ES&H professions and industry representatives who are affected by its implementation are being introduced to CB strategies. Multiple workshops in the United States have sought to recruit stakeholder participation and input on the potential utility and development of a national CB strategy [Nelson and Zalk 2004a,b].

2.1.3 Replacing Good Science with Vague Controls

2.1.3.1 Weakness. Given the existence of a refined profession dedicated to ensuring safety and health based on scientific knowledge and practices, what is the motivation seemingly to replace it with a vague and potentially harmful simplified approach? This is an especially complicated question to address in the United States where more than half of the world's trained and qualified IH professionals reside. The IH profession is accustomed to working with modern sampling equipment, refined analytical methods and abilities, and a network of professionals with expertise. Yet, most safety and health professionals in the United States would admit that many workers are left unprotected, despite protections in place to assist in addressing these situations [Kalisz 2000]. These protections, provided by Federal and State OSHA plans, NIOSH within the Centers for Disease Control and Prevention (CDC), U.S. Environmental Protection Agency (EPA), and organized labor groups, include workplace safety and health standards and guidance designed to address hazards to workers and the public.

A system like CB, though well intended and promising, may have flaws. The resulting control guidance obtained using the CB approach could be less useful and protective than that recommended by a professional. The introduction of CB alternatives could lead management to consider replacement of ES&H staff with such qualitative risk management strategies and tools, justifying the latter as being more economically efficient. While introducing a CB system might seem relatively easy in theory, ensuring controls are properly implemented and evaluated for their effectiveness are more difficult and economically challenging endeavors.

2.1.3.2 Strength. It is a conundrum that IH professionals who best understand how to protect the worker and recognize that a majority of the workforce will never benefit from their profession's advice may also be hesitant to endorse CB approaches. In workplaces where IH support may never extend, alternative approaches and mechanisms for providing control-focused guidance that can be easily understood and applied hold great promise for reducing occupational disease and illness. The CB strategy has been described as an opportunity to simplify the best of scientific information into a format that is accessible to the multitudes [Tischer et al. 2003a]. Good IH science in practice is expensive. It is this expense that renders it inaccessible to so many. There is no intent in the development of the CB strategy to have it replace good science [Oldershaw 2003]. Yet the strategy of studying objectively the potential utility of CB within the United States, identifying areas for improvement (for example validation of control effectiveness), and recognizing those situations where it should not replace expert consultation has the objective of providing a practical and effective approach for risk assessment and management of workplace hazards.

2.1.4 Affecting Professional Industrial Hygienists

2.1.4.1 Weakness. The primary apprehension of many professionals is that CB will weaken and possibly eliminate the profession. The best controls to prevent work-related disease and illness are put into place by a professional industrial hygienist. Managers of industries of all sizes already have financial burdens to overcome, and ES&H priorities and budgets are often impacted by funding constraints [Burton 2004]. Under such pressures, the U.S. system is moving in the direction of encouraging the pure IH specialist to become an ES&H generalist [Nighswonger 2001]. Offering managers an option like CB may provide an economically wise option that may be perceived as accelerating the transition away from IH specialists. Additional concerns have been raised to suggest that implementing a CB strategy has the potential to offer solutions without oversight and controls with potentially harmful consequences. This is especially an important perception among consultants. Many make their living by offering expertise to SMEs to reduce the financial effect of maintaining a staff. If an inexpensive option is made available, especially if supported by most of the key ES&H-related organizations in the United States, it becomes an easy option. In making this easy economic decision, the IH profession will become further diluted. The resulting lack of demand will continue the pervasive closure of university IH programs and with it will go the future of the IH profession.

2.1.4.2 Strength. The IH specialist is an occupation which is currently declining in population, and professional organizations have predicted this trend may continue. One of the fundamental failures of the profession is the inability to communicate and promote its responsibilities and its value to the greater society [Burton 2004]. The CB strategy, should it reach a point that it is a viable commodity for the nation's industries, may provide such an opportunity to strengthen and promote the IH profession. For CB to be implemented nationally, part of this system must bring to employers and managers a package that describes the role of the industrial hygienist in businesses with the potential for work-related exposures [Maidment 1998]. If IH professionals educate the manager of a small business about a simple process that can help protect the health of workers, and if it is implemented, then they are achieving the intent of their profession in absentia [Money 2003]. As part of an appropriate CB strategy, there must be a threshold to indicate when professional IH consultation is necessary. Therefore, the CB strategy is one that will seek to raise the profile of the industrial hygienist as an integral part of the workforce while maximizing resources and guidance for promoting occupational safety and health.

2.1.5 CB as a Replacement for OELs

2.1.5.1 Weakness. Thousands of chemicals remain unregulated without specific OELs [Topping et al. 1998]. Further, it is argued that it is infeasible to do all the studies necessary to derive and assign accurate OELs to cover this growing burden [Kromhout 2002a]. For these reasons, use of a qualitative risk management is an appealing option. Yet for some this option is viewed warily, based on the belief that moving in this direction will convince management that scientifically derived worker protection systems, such as the internationally acclaimed ACGIH TLVs, NIOSH Recommended Exposure Limits (RELs), and OSHA Permissible Exposure Limits (PELs) are unnecessary or no longer practical. To those with the scientific understanding of the processes at work to derive appropriate exposure limits to protect the health of the workforce, the possibility of eliminating the OELs is unconscionable.

2.1.5.2 Strength. Setting OEL values in the United States, such as TLVs® and PELs, is a labor and resource intensive scientific process. The value of the CB strategy to the OEL setting systems is two-tiered. For the reasons stated above, the IH profession can be strengthened by educating the public of the value and role of its work [Burton 2004]. Integral to the role of the professionally trained and educated industrial hygienist is the reference to and reliance upon technical and scientifically derived exposure limit values for assessing the work environment. As a supplement the concept of OELs, a successful CB program will give a newly educated, broad spectrum audience a far better understanding and respect for exposure prevention [Guest 1998; Russell, Maidment et al. 1998]. The CB strategy can provide the mechanisms to assist in managing the increasing numbers of chemicals [Balsat et al. 2003; Swuste et al. 2003; Money 2001a; EC 2001; Vincent and Bonthoux 2000; UIC 1999]. As part of the CB validation protocol it will be essential to include personal monitoring as a tool in validating that controls are indeed commensurate to exposure potential for each of the toolkits that are considered for field practice and application [Oldershaw 2003; Maidment 1998].

2.1.6 Exposure Assessment Versus Exposure Control

2.1.6.1 Weakness. Following the discussion of the weaknesses associated with long-term CB implementation, a look at the short term is appropriate. One path forward for the CB strategy would emphasize exposure controls and solutions for workplace hazards. Some of the toolkits that are currently in practice and being created are missing an interim step important to the sciences that comprise the greater occupational and public health professions. Exposure assessment and risk assessment are essential applications of toxicology and epidemiology concepts. These applications rely on personal exposure measurements as a link to establish the probability of work- and environmentally-related illness. These results are essential for the prioritization and organization of occupational and public health budgets and deriving which approaches are most effective and economically viable [Kromhout 2002b]. By contrast, the CB approach is perceived to allow risk assessment and management to proceed in the absence of personal exposure monitoring. The IH profession, especially in the United States and other developed nations, relies on exposure monitoring to indicate the need for, and the effectivess of, control processes. Given the resources to perform such monitoring, it has been argued that it is a moral and ethical obligation to do so; yet more than 90% of the world's workers work in establishments that do not have access to such resources and ES&H professionals [Takala 1999].

2.1.6.2 Strength. Exposure assessment based on personal monitoring is an essential tool of the practicing industrial hygienist. It is perceived that the CB strategy does not use or rely on such monitoring for exposure assessment ; on the contrary, it is a necessary part of the validation of toolkits to ensure controls are appropriate as put into practice [Tischer et al. 2003a; Money 2003; Swuste et al. 2003]. A key point for COSHH Essentials is that this CB model is not intended to replace exposure assessment, interpretation, substance, and chemical control [Oldershaw 2003; Nelson and Zalk 2004a,b]. For some tasks the estimation of potential exposure as an interim step before establishing controls will not be feasible. Point source emissions that do not involve the use of bulk chemicals, such as silica exposures in construction work, are an important example of an application where moving directly to exposure controls based on the task performed is the best path forward for the CB strategy. Controls that are tied to these specific tasks require an established exposure assessment in the development of a particular toolkit. Most of the workplace scenarios that have been characterized in previous exposure assessment studies support the CB strategy by educating the industrial hygienist with an understanding of which tasks, activities, or workplace scenarios justify specific controls. Using silica exposures in mining or construction as examples, the appropriate control recommendations and reduction of exposures resulting from control implementation have been characterized in historical studies involving exposure monitoring and analytical methods [Goldsmith 1997; Flynn and Susi 2003; Rappaport et al. 2003; Donoghue 2004]. Also, since further exposure assessment will be required for CB validation, it can be argued that this process will contribute to the volume of task-related exposure assessments [Jones and Nicas 2004, 2006a; Kromhout 2002a; Maidment 1998]. A further contribution of CB implementation can be to increase exposure assessment applications for field practice.

2.1.7 Predicting Exposures and Implementing Controls

2.1.7.1 Weakness. A single application is an excellent example for clarifying weaknesses of the CB approach. Given a chemical's identity, R-phrase, volume, and temperature of application, an appropriate exposure control option can be determined. The COSHH Essentials exposure prediction model is generic in nature and, through its emphases on simplicity and transparency, may have sacrificed reliability and accuracy [Tischer et al. 2003a]. The less technical systems, which are the majority of the toolkits currently in development, do not use an interim work area exposure prediction. An area exposure estimate has been technically and scientifically proven to be a poor surrogate for an actual personal monitoring result obtained within a worker's breathing zone [Kolanz et al. 2001]. In addition, such estimates may not account for the dimensions of the work space, whether the chemical will be sprayed, rolled on, or poured in, over how much time is it transferred, how much is applied at each manufacturing step over time, and whether there is an extraneous step such as welding or treating of the chemical after its application [Tischer et al. 2003a]. Without knowing the use of the chemical in practice, and the variability in this practice among workers and between work areas, the value of the control is questionable [Swuste et al.

2003; Kromhout 2002b]. Comparisons of the SQRA (Singapore) with the COSHH Essentials-based International Chemical Control Toolkit indicate that, for the majority of the 27 processes selected, the toolkit estimated higher risk relative than the SQRA indicating more recommendations for conservative (i.e., more protective) controls [Yap 2004]. Ultimately this supports the need for professional judgment to utilize exposure assessment for determining control strategies, especially when training and teaching how to perform the appropriate application of such controls.

2.1.7.2 Strength. For point source exposures, toolkits will either use exposure prediction for the task-related controls suggested or will have shown that implemented controls are effective for reducing exposure regardless of predicted exposure. The parameters of a particular task performed by a single person are important, but more important is the reduction of exposure even if the end result may be above established OELs [Jones and Nicas 2004, 2006a; Kromhout 2002b]. As part of the CB validation strategy, further exposure assessment will not only be an essential confirmation of the success of implemented controls but will also serve to improve the given toolkit's information basis to be applied in subsequent revisions of the toolkit [Oldershaw 2003]. This would then benefit not only the individual worker, but would also provide scientific and technical information to practicing IH professionals. Toolkits addressing bulk chemical processes that seek to estimate predicted exposures may have problems with the lack of data for validation [Money 2003]. The validation protocol within the CB strategy may then provide more professional judgment for SMEs than already exists.

2.1.8 Validation and Maintenance of Implemented Controls

2.1.8.1 Weakness. The implications of providing control solutions are a serious consideration for the IH profession. The costs of a local ventilation control may be cost prohibitive for a small business when a simple work practice modification or chemical substitution would suffice [Jones and Nicas 2004, 2006a]. How is the IH profession to oversee that PPE recommendations are implemented appropriately? If the wrong glove material is recommended, or an inappropriate respirator type is chosen, the level of protection afforded a worker may not be sufficient and would not be detected according to the toolkit's formula [Guest 1998]. Small volumes of a liquid chemical used in practice can contain de minimus quantities of highly toxic constituents that may not be listed on an MSDS (e.g., an epoxy that contains periodically-reformatted chemical forms of a sensitizer that may not have an associated R-phrase). The consequence of such scenarios is to render a false level of safety [Jones and Nicas 2004, 2006a]. The CB models based on COSHH Essentials have also been shown to indicate more conservative control solutions based on comparisons with the SQRA method that uses personal exposure monitoring data for deriving risk levels [Yap 2004]. Presuming that the recommended controls are indeed appropriate, how will IH professionals know they are implemented? If they are implemented, how is it known, in the case of ventilation, that they are assessed for effectiveness? If effectively implemented, how do they know they will be maintained? If maintained, how is it known the application would be reassessed if the process is modified, chemicals substituted, or formulations changed entirely? The dynamic nature of industry and manufacturing does not quite fit with brief managerial consideration of safety and health in the absence of onsite consultation. The current CB strategy relies on the goodwill and concern for its workers of nontechnical overseers who are likely be under-trained and ill-equipped with appropriate information to validate and maintain the best controls [Tischer et al. 2003a; Maidment 1998]. As indicated by the current NIOSH research, even under the best circumstances, a portion of the workforce will be affected by an implemented CB strategy that will be wrongly assuming that the work they are performing is inherently safe. Without CB, workers unsure of exposure levels must rely on their own knowledge and awareness of hazards to protect themselves. This possibility may be seen as a better alternative than being incorrectly informed that their work is safe based on CB determinations.

2.1.8.2 Strength. The need for validation of toolkits and the CB strategy conceptually has been previously stated, and the benefits to the profession and workers emphasized. A limitation of the current CB strategy is that it is static, whereby a dynamic system is required to ensure that the controls implemented and the managerial oversight are maintained over time. Consequently, validation must not only consider the effectiveness of a given toolkit and its controls, it must also seek to validate and compare the various possible methods of implementation and the construct within which they are introduced to both employers and workers. This effort will result in a task-specific database that integrally involves CB strategies in effective control solutions.

2.1.9 Defining Validation Terms for CB

A significant issue for the implementation of CB is the accuracy of the decision logic. Under-prescription of control could lead to serious illness, even death, while over-prescription could lead to considerable unnecessary expense. Future identification of either case could lead to a loss of confidence in the system as a whole. Assurance can be provided by validation. Validation involves testing a hypothesis that the decision logic is accurate. It is important that decisions are made a priori regarding the degree of accuracy required and the confidence. Each step of the CB strategy may be validated independently of the others.

2.1.9.1 Exposure Prediction. Generic CB strategies such as COSHH Essentials and Stoffenmanager predict exposures of workers in the absence of any controls. In theory, these predictions could be tested by measuring exposures prior to the application of the CB strategy. However, difficulties exist in applying this test. For example, in the United States it is rare to find workplaces without any controls, and it is also rare to find exposure data of the quality required to estimate accurately the full range of worker exposures.

The data used to calibrate the exposure prediction methodology probably came from workplaces that had at least general dilution ventilation. It is therefore reasonable to assume that exposures measured where general dilution ventilation exists can be used to test the system. In cases where engineering controls are already in use, they could be discontinued for the purpose of this test, as long as this can be done without risk to workers. In order to properly characterize the entire range of workers' exposures for the task or process under study, measurements must be taken to assess inter-worker, intra-worker, and inter-worksite variation. Repeated measurements involving several randomly selected workers are required, generally around 20 measurements on 10 workers when establishing the average and range. If it is considered necessary to focus on the top 5% or 10% of exposures, then larger numbers may be required, or perhaps a model can be introduced to evaluate the extreme range of the likely log-normal distribution.

2.1.9.2 Hazard Prediction. Hazard is generally described in terms of the toxicological endpoint of concern, for example the description associated with a specific R-(Hazard) phrases.

Such phrases give the critical endpoints of disease, but say little about the relative severity of equivalent exposures to different chemicals with the same hazard identification. For example, acetic acid and trichloroacetic acid are both irritants, but their ACGIH TLVs® vary by an order of magnitude. Where additional toxicological data exist, they can be used for further assessment of the hazard ranking methodology.

2.1.9.3 Control Recommendations. The final outcome of all CB toolkits is the recommendation of controls. The accuracy of the outcome regarding control determinations derives from recommendations of subject matter experts. The CB control recommendations can be tested by matching them against expert recommendations. This is best done using scenarios where the exposure predictions and hazard predictions have already been tested and found to be appropriate.

2.1.9.4 Training. A goal of CB is to provide a system that can be used by nonexperts in the field of IH practice, so that training in the use of the methodology is an essential part of many CB strategies. Training programs should be evaluated with respect to the following: target (e.g., was the training provided to those with authority to recommend or make changes?), reception (e.g., was the training offered sufficiently often, by a source considered trustworthy, in an environment conducive to processing?), and outcome (e.g., was the training implemented, and was the system used in the correct manner?). Evaluation of training effectiveness is an important step to provide feedback addressing these and other relevant questions.

2.1.9.5 Control Implementation. Once controls have been implemented, it is necessary to discover whether they were correctly implemented, whether sufficient knowledge and expertise exist to maintain them, and to evaluate their efficacy when necessary (e.g., when processes change). Routinely scheduled maintenance and evaluation can ensure this.

2.1.10 Additional Components That Must Be Validated or Verified

Development and implementation of CB requires a number of steps related to creation of the model, application of the model, installation and operation/maintenance of controls, post-control monitoring, and failure analyses at each step of the CB process. Specific steps include the following:

- Assignment of an R-phrase or other toxicological rating to a substance
- Assignment of R-phrase to hazard bands
- Reporting of R-phrase by supplier
- Reporting of dustiness/volatility by supplier
- Understanding by user, including R-phrases, quantity of substance in use, and dustiness/volatility of substance
- Construction of model to combine quantity in use and dustiness/volatility to predict hazard band
- Overall use of model by user to determine the control guidance level
- Selection of CGS
- Installation/operation/use of controls to reduce exposures

Validation of a CB model will require efforts to consider and characterize these activities.

2.2 Determine the Barriers to, and Utilities for, Implementing CB to Address Safety and Health Hazards in U.S. Workplaces

Among potential barriers to the implementation of CB strategies in the United States are legal implications, concerns about devaluation of worker protection, and application of R-phrases. The creation of a dynamic process to ensure quality of implementation over time and the use of CB strategies within U.S. regulatory and management schemes could facilitate the implementation of CB.

2.2.1 Barriers to Implementing CB

2.2.1.1 Legal Implications. It is impossible to discuss any new system that seeks to protect workers in the United States without addressing legal considerations. One challenge relates to the recognition that application of a generic CB system may provide practical tools for managing and reducing hazardous exposures, with possible exceptions where it fails to meet established criteria for some fraction of workers [Jones and Nicas 2004, 2006b; Money 2003; Kromhout 2002b]. Such limitations indicate weaknesses in a given toolkit's application. Such limitations may lead to inappropriate levels of workplace protection and contribute to occupational illness and injury, as well as employer liability.

2.2.1.2 Devaluation of Worker Protection. CB seeks to offer the best of a good exposure reduction process, because the known and scientifically founded parameters of a perfect system are not economically viable or available. Research indicates that the guidance from CB models will likely either under-protect the worker or prescribe over-protective controls in a certain percentage of cases [Jones and Nicas 2004, 2006b]. Creating a minimal level of protection with the CB strategy for the worker performing a common task may be accomplished, but at the risk of ignoring the variability between workers.

2.2.1.3 Use of Standardized Hazard Statements in Control Banding. Under the CB model used in COSHH Essentials, the hazard and degree of severity of hazard are obtained from the phrases on European labels and safety data sheets. These are referred to in the European classification and labeling system as R-phrases, and they are required for posting on labels and safety data sheets. The European system has been harmonized among its countries for many years. The R-phrases are standardized, and the EU also publishes classifications for many chemicals with an indication of the appropriate R-phrases.

The U.S. classification and labeling system in the workplace is the OSHA Hazard Communication Standard (HCS). The HCS requires classification of chemicals according to the hazard criteria in the standard and also requires the label preparer to include appropriate "hazard warnings" on the chemical label. It does not specify the language to be used to convey the hazard information since it is a performance-oriented standard. It also does not require that the label phrases appear on the safety data sheet for the chemical. The U.S. definitions of hazard are similar to the EU's but not identical. Thus the R-phrases they have assigned to particular chemicals may or may not accurately reflect the hazard of the chemical under U.S. law. Therefore, one cannot simply use the R-phrases for a chemical from the EU system to apply CB in a U.S. workplace.

In order for CB to work, the use of standard hazard statements linked to specific criteria is necessary for consistency and the determination of the proper level of control. Many companies in the United States have developed their own databases of standard phrases that they use to convey hazards for their products. Some companies in the United States have used the hazard information on U.S. safety data sheets and applied their professional interpretation of the data to link it to an EU R-phrase and then used the phrase to apply CB. Doing this successfully would require a level of professional expertise and judgment in toxicology and other disciplines that would be limited to larger North American companies in most situations. The lack of this piece of information—the standard hazard statement—for the CB equation is a significant impediment to successful implementation of CB in the United States. Ready availability of standardized phrases linked to U.S. hazard criteria is necessary to ensure the possibility of widespread application of CB, particularly in small businesses.

Resolving some of the challenges associated with hazard classification, labeling, and communication may occur with the adoption of the Global Harmonization System for classification and labeling of chemicals (GHS). The GHS is a common and coherent approach to classifying the health, physical, and environmental hazards of chemicals, and to communicating the hazards through labels and safety data sheets (see Section 2.4.4). GHS includes a core set of label elements and has harmonized hazard statements for each category and class of chemicals covered. It also has a harmonized approach to classifying mixtures of these chemicals. Adopted by the United Nations in 2003, the GHS is being considered for adoption in the United States, the EU, Canada, and many other countries. Global implementation of the GHS would thus provide an international system upon which to base CB. The ILO has included the GHS hazard categories in its International Chemical Control Toolkit in recognition of this. Action is also being taken to modify the roughly 1600 ICSCs prepared under the IPCS to follow the GHS criteria for classification and the harmonized hazard statements for the most commonly used chemicals. Implementation of the GHS in the United States was introduced by OSHA in September 2006 in an advanced notice of proposed rulemaking for revising the Hazard

Communication Standard, requiring use of standard hazard statements on U.S. labels as well as on safety data sheets.

2.2.2 Utilities for Implementing CB

2.2.2.1 Creation of a Dynamic Process to Ensure Implementation and Maintenance Over Time

Current efforts for creating a CB process have focused almost entirely on evaluating and perfecting existing toolkits. As shown in the current NIOSH research discussed in greater detail above, this focus may be flawed for national implementation at this time because it is a static approach for initial applications without consideration for the multiple factors that consistently affect change in U.S. manufacturing and other industrial sectors. Therefore, a parallel effort is necessary to create a dynamic system for the CB strategy that seeks to maintain this concept over time for both the controls implemented and the managerial oversight to ensure CB does not fall into misuse, improper application, or lack of implementation entirely. Essential to the utility of a dynamic system is the protocol for validation to ensure that assessments and resulting control recommendations are appropriate and effective, and to identify exceptions and areas requiring further evaluation and improvement [Guest 1998; Yap 2004; Tischer et al. 2003a; Jones and Nicas 2004, 2006a,b; Brooke 1998; Loughney and Harrison 1998; Palmer and Freegard 1996].

Under the current static CB approach, it is anticipated that some employers will tout the benefits and use of CB without being in a position to implement or enforce its use. An alternative dynamic CB system should be incorporate management considerations that would facilitate putting the CB strategy into practice. This system should also be accompanied by a method of measurement for the extent of institutional implementation, its ability to adapt to changes over time, as well as a quantifiable determination of the level of successes and reduction of exposure potentials. This dynamic strategy should be developed with a theoretical approach that envisions cost not being a consideration. It should ensure that all tasks, chemicals, and exposures involved are considered, so the properties, toxicity, application, and conditions during applications are part of the decision matrix. Creating this system with a task force of safety and health professionals working in concert with managerial oversight and workplace employee representatives will facilitate the best use of CB to maximize its effectiveness, consistent application, and economic efficiency. An example of a vehicle for this approach is the American National Standards Institute (ANSI) Z10 committee (Table 17). This should all be achieved with the understanding that industry specific, worker-influenced solutions have the best possibility of being applied, achieving success, remaining in place over time, and having a mechanism for ensuring commensurate controls are in place regardless of changes in tasks, processes, products, and the inevitable workplace rotation of affected worker populations.

Table 17. Current registered input to the ANSI Z10 review committee

Pertinent Sections from ANSI Z10 with comments
• 3.2; Employee participation (ID tasks, risks, & possible controls) — no mention of evaluating exposures
• 5.4; Document & Record Control Process — if CB in an OHSMS, it becomes part of the process
• 6.1; Monitoring & Measurement: F. "Other methods" — doesn't rule out semi-quantitative/qualitative
• 6.3; "System" Audits: evaluating activities & corrective actions - recordable CB process fits audits
• 6.4; Track actions for effective implementation — possible weak point with CB, needs strengthening

2.2.2.2 OSHA and Its Voluntary Consultative Services. The U.S. OSHA Consultation Program to Small Businesses was first promulgated over 30 years ago, and has served as an effective mechanism for promoting safety and health guidance and solutions for the small business audience since. However, fear of government intervention and penalties prevents many small businesses from utilizing this service [Kalisz 2000]. As a means to overcome this reluctance among small businesses, introducing practical qualitative risk assessment and management tools such as a CB strategy may provide opportunity for OSHA to form strategic partnerships, possibly recognizing and rewarding successful control implementations in the process. Results of effective partnerships might contribute to a solutions database and provide effective advertising of services focusing on worker safety and health education [Topping 2001]. OSHA could be assisted in accomplishing compliance by helping businesses to develop guidelines. This could create a larger demand and respect for these consultative services, emphasizing the assistance to businesses and working toward cooperative solutions [Money 2003]. In building support for the partnerships and exploration of CB applications, the involvement of organized labor representatives is paramount.

This envisioned CB strategy for implementation synchronizes well with the existing OSHA Consultation Program offering free consultation services largely funded by OSHA. This program offers employers the opportunity to find out about potential hazards at their worksites, improve their occupational safety and health management systems, and even qualify for a 1-year exemption from routine OSHA inspections. Recent changes in 20 CFR* Part 1908 as it was amended in 2000 reflect many of the underlying tenets of the CB strategy: (1) provide for greater worker involvement in site visits, (2) require that workers be informed of the results of these

* *Code of Federal Regulations*. See CFR in references.

visits, (3) provide for the confidential treatment of information concerning workplace consultation visits, and (4) update the procedures for conducting consultation visits. Specific task-based hazard guidance concepts associated with CB might also have utility for the OSHA Consultation Program for providing guidance to target smaller businesses. This can be accomplished while communicating the distinction between OSHA safety and health consultation services and enforcement efforts.

2.3 Implementing a Risk Management System in the United States that Includes CB Strategies

The implementation of CB strategies in the United States for qualitative risk assessment and management requires additional research and development. Topics areas for further exploration include the provision of national-level guidance and coordination, pilot projects at the State level, and expansion of the ORM toolbox to include more chemicals and ergonomic, safety, and environmental concerns. Cooperation with international efforts to implement CB can strengthen efforts in the United States through bilateral sharing of research and experience. Linking CB strategies with Occupational Safety and Health Management Systems and the GHS will add value.

2.3.1 Can Toolkits and ORM Toolboxes Reduce Occupational Exposures to Protect the Health of Workers on a National Basis?

2.3.1.1 Current Chemical Agents Scope

2.3.1.1.1 Develop a National Control Banding working group. Such a group would be charged to create a validation process that will appropriately evaluate the existing toolkits and focus on applications within selected industrial sectors and specific trades. One objective of the validation group is to emphasize field IH input for identifying needs for improving toolkits and determining the scope of their implementation. Part of this validation strategy will consider measurable parameters for ranking hazards, the prioritization of controls, and the effectiveness of their application. Because the emphasis on personal sampling requirements as part of a validation strategy is essential, this approach should be developed using statistically supported bases and be coordinated with research that will focus on prospective and retrospective epidemiological studies. Validation efforts should simultaneously compare and contrast the success rates of different approaches to implementing a given CB system. At present, data are not available to allow appropriate validation of CB toolkit models [Jones and Nicas 2004, 2006a,b; Money 2003; Tischer et al. 2003a; Kromhout 2002b; Maidment 1998].

2.3.1.1.2 Small business implementation. While the validation strategy is in development, it is possible to utilize toolkits to provide hazard guidance in small business trades and industrial sectors. A practical approach could involve comparison of the different existing toolkits as well as the type of system within which it is implemented [Oldershaw 2003]. The different State OSHA plan systems may provide opportunities to apply a toolkit through demonstration or pilot programs in a few different States. If a State OSHA approach can integrate partnerships with trade organizations, organized labor groups, educational institutions, and government agencies, then a pathway would exist to build this model with a participatory approach by including both workers and employers in its development [Money 2003]. This approach fits well with the intent of the OSHA Alliance Program created in 2002 to enable organizations committed to safety and health to work cooperatively with OSHA to prevent illnesses, injuries, and fatalities in the workplace. Seeking and providing end-user input as part of this focus on the workforce will help improve the final CB product and determine when its use is most practical and how best to implement it.

2.3.1.2 Expanding to an ORM Toolbox

2.3.1.2.1 Expand "chemical control" beyond current scope. This effort should begin by including point source emissions that do not involve the use of bulk chemicals, such as silica exposures relating to construction work. Construction work is an important example of an application where moving directly to exposure controls based on the task performed is the best utilization of the CB strategy. Using the construction industry as an important emphasis area would allow expansion of IH aspects to include other chemical and physical exposures and perhaps addressing biological exposures such as mold initially. Validation of controls tied to specific construction tasks that have an established exposure assessment would be linked to achieving target reductions in exposure on a task-by-task basis. The development of a complete ORM toolbox will enable applications that cut across industry barriers. For example, silica dust exposures in construction have some similarity to conditions and activities in some mining processes. Experience with exposure characteristics, processes, and controls in both industries may be transferable and could contribute to development of a solutions database with established toolkit and toolbox controls [Jones and Nicas 2004, 2006a,b; Guest 1998; Brooke 1998].

2.3.1.2.2 Develop Ergonomics Toolkits based on existing national models. One potential application of the CB strategy in the early stages of exploration is the reduction of musculoskeletal disorders resulting from ergonomic exposures. The more traditional applications for chemical toolkits seek to address an extremely large and growing inventory of chemical substances. Chemical production involves the introduction of new constituents that may never be fully researched and adequately characterized with regard to exposures, toxicity, and control options. In contrast, ergonomics has a finite group of well-researched and defined risk factors and effective programs [Stewart et al. 2005; Zalk 2003]. In theory, a comprehensive collection of ergonomics toolkits could be developed, validated, and implemented prior to creation of a parallel chemical agents approach. For applications in this arena, the CB strategy could promote the use of practical tools for assessing and reducing risk based on recent advances in participatory ergonomics. Using the model described above for creating and implementing a CB Strategy for ergonomics is a proposal for the best first step. Compiling a repository of well-researched, validated, existing models in the United States could lead to a solutions database for musculoskeletal hazards and ergonomic control options.

2.3.1.2.3 Investigate expanding to safety and environmental parameters. Expansion of the ORM toolbox could also encompass the ES&H multidisciplinary concepts impacting U.S. business establishments. The example of creating a Construction ORM toolbox could serve as an appropriate initiation for a system that would incorporate occupational safety and health requirements at a given worksite and include an additional focus on traumatic injuries. In this system an appropriate context for a safety-related toolkit would probably emphasize integrated training that offers a simplified approach to lessons learned by accumulated tasks within a given trade. As an additional application, an environmental toolkit could be developed to assist employers and educate workers on the benefits of waste management for improvement of the air, soil, wastewater, and waste disposal streams. In developing this system, it is essential to involve stakeholders to define minimum performance standards, and to include this input in the development of simplified training programs. For implementation in the United States, it would be progressive to incorporate pictorial training consistent with the GHS symbology to reduce the need for multiple translations. A challenge facing industrial hygienists in communicating exposure reduction successes is the dearth of appropriate yardsticks for measuring program benefits of a disease prevented. Possible solutions to address this challenge include better surveillance and use of appropriate metrics to track the effectiveness of hazard control interventions.

2.3.1.3 National CB Strategy Implementation

2.3.1.3.1 Explore Creation of a National CB Program. To coordinate multiple activities supporting a control-focused risk management initiative, each requiring field research, validation, feedback, and improvement, would require coordination to oversee the process and track progress. Participation in this effort by stakeholders, labor organizations, and the ES&H organizations would be integral to its success. Part of this strategy would involve education for national ES&H and labor organizations to provide them with the foundation for a CB strategy and their role in its development, validation, and implementation. Insurance companies, workers' compensation agencies, and multinational companies could also contribute by sharing expertise, resources, and communication networks to prioritize efforts and promote the application of control-focused solutions to occupational hazards.

The scope of such a strategy necessitates linking with other similar committees and CB strategy entities internationally. A coordinated, consistent effort could maximize utility of limited resources and encourage harmonization in an increasingly global economy. As part of this strategy, exploring the twinning of Developed Countries with Developing Countries for trial implementation, with a focus on communicating and sharing of successes, may also assist in limiting the need for translating programs that are developed in native languages.

2.3.2 Can Toolkits and ORM Toolboxes Reduce Occupational Exposures to Protect the Health of Workers on an International Basis? How Can International Cooperation Assist in the Creation of Toolkits and ORM Toolboxes for Use in the United States?

2.3.2.1 Twinning Developed Countries with Developing Countries

2.3.2.1.1 Current chemical agents scope. An effort to investigate twinning concepts was begun at the Control Banding Practical Applications Workshop, held June 13–16, 2004, in Utrecht, The Netherlands. This meeting was coordinated as part of the WHO Collaborating Centers Occupational Health Network (WHOCC) 2001–2005 Work Plan's Task Force 10 on Preventive Technologies. This event resulted in planning to create and implement twinning strategies for pilot projects with CB for South Africa, Benin, and India. Developing and overseeing of these twinning strategies and training protocol would be coordinated and economically assisted with more established programs in developed countries, such as those in the United Kingdom, the United States, and The Netherlands. Attendees included leadership and representatives from the International Technical Group on CB and attendees from The Netherlands, Switzerland, India, Benin, South Africa, Brazil, Central America, Canada, and the United States. This cooperative effort is a model for future cooperative work between developed and developing countries. International collaboration can appreciably strengthen national capabilities for the protection of workers' health and the environment. Sharing knowledge and experiences will also limit duplication of efforts and instead will build capacity by combining resources. It can also serve as the best method to test and improve existing toolkits, to identify the steps necessary to successfully build new toolkits, and eventually to create the blueprint for developing complete ORM toolboxes.

2.3.2.1.2 Expanding to an ORM Toolbox. For cooperative efforts internationally, eventually a focus on large scale industries in developing countries will be necessary to link ORM toolbox needs in developed countries. Selection of appropriate industries will help determine the effectiveness of exposure prediction related to some existing toolkit applications. For practical purposes, activities and progress implementing elements of CB should consider the guidance presented in the International Technical Group's Implementation Plan [Appendix C]. Such efforts would be consistent with the WHOCC Work Plan for 2006–2010 expressing international commitment to expanding the CB strategy to an ORM toolbox through the development of a new Task Force for Preventive Technologies. The initial draft of the 2006–2010 Work Plan was drafted as part of the IOHA 6th International Scientific Conference on Occupational Hygiene, which was held in September 2005, in South Africa. This IOHA conference also hosted the 3rd International CB Workshop.

2.3.3 Can These Risk Management Systems Be Linked to Current OHS Management Systems?

2.3.3.1 Fitting CB into occupational safety and health management systems. Since the International Organization for Standardization (ISO) is an existing network of the national standards institutes in 147 countries, an appropriate CB strategy with international relevance could benefit from consideration as a potential standard within this framework. With the success of ISO 9000 for working with quality management and ISO 14000 for working with environmental management, a natural extension of this concept would be to include safety and health. The Occupational Health and Safety Assessment Series (OHSAS), the OHSAS 18001–2, is a management system that seeks to help organizations control occupational safety and health risks. Similar to the objectives of the CB strategy, OHSAS 18000 series is a method of assuring conformance with an occupational safety and health policy. A critique of the OHSAS 18001 was performed for the ILO by IOHA (the resulting report can be accessed at the IOHA Online

Library for WHO and ILO documents at http://www.ioha.net/). Strengths identified within the critique include long-term employer savings by using risk assessments for cost avoidance, reducing workers compensation and medical costs, focusing on proactive prevention to reduce safety and health liabilities, and setting safety and health dedication apart from other traditional areas of business and trade. Linking the CB strategy within an existing system like OHSAS could provide a mechanism for toolkit and toolbox implementation to ensure it is maintained and improved within a management system that can be assessed at appropriate intervals.

Part of integrating CB into a business model is overcoming the difficulties safety and health professionals have in communicating the value of their services. The collective professions of environmental and occupational safety and health generally have limited ability to understand and speak the language of businesses by converting issues directly into financial terms [Schulte 2004]. One possible exception is for those professionals in the pharmaceutical industry where this approach has been successful, and consequently could serve as a model to be followed as a formal means of communication in other industrial sectors. In addition, further benefit could be derived if workers' compensation and insurance organizations could promote and lead the education efforts for learning how best to speak the language of business [Schulte et al. 2004; Ennals 2002]. Self-insured multinational organizations have already learned the value of this process by investing in research in improving return-to-work rates [ILO 1998]. Therefore, harmonizing CB strategies with the development of the American National Standards Institute (ANSI) Z10 version of OHSMS in the United States could potentially improve the effectiveness of both efforts.

2.3.4 Are These Risk Management Systems Compatible with the GHS?

2.3.4.1 CB Compatibility with the GHS for the Classification and Labeling of Chemicals. The GHS was developed as the result of an international mandate adopted at the United Nations Conference on Environment and Development (UNCED) in 1992. The goal was to have such a system developed by the year 2000, including criteria for the classification of hazards, labels, and safety data sheets. The work was to build on existing systems in the United States, Europe, Canada, and the United Nations transport systems. Classification and labeling laws are based on countries recognizing that the quantity of chemicals in commerce is so extensive that no country can effectively regulate each one individually. In the United States, for example, it has been estimated that some 650,000 hazardous chemical products are used in American workplaces. Having laws that require information to be transmitted to users regarding these chemicals is one way to ensure that steps can be taken to provide protection from their hazards. While similarities exist among international hazard classification systems, the national, regional, and international requirements are different enough to require multiple classifications of a chemical to be shipped to different countries, as well as multiple labels and safety data sheets. Therefore, the mandate from UNCED was to encourage countries to work together to eliminate these differences by harmonizing their requirements, maintaining or enhancing protections in the process, and eventually providing the opportunity to eliminate technical barriers to trade in this area.

Development of the GHS involved 10 years of effort by multiple countries and international organizations. Completed in 2002, the maintenance, updating, and implementation of the GHS are assigned to a new United Nations Subcommittee of Experts on the GHS. The United States was an active participant in the development of the GHS, both through government participation as well as the participation of relevant stakeholders, and is a member of the United Nations Subcommittee. An international goal to have as many countries as possible implement the GHS by 2008 has been established by both the Intergovernmental Forum of Chemical Safety and the World Summit on Sustainable Development.

As emphasized above, an important obstacle for the United States in moving forward with the GHS is the lack of standardized hazard statements on labels and safety data sheets that are analogous to the system used by the EU. This should be seen as a true obstacle for CB implementation in the United States. Nevertheless, the availability of an internationally approved system to classify chemicals and prepare harmonized labels and safety data sheets provides a strong impetus for adoption. The additional impetus to adopt the GHS is provided by the potential widespread applications for CB in the United States.

2.3.4.1.1 GHS and CB. Although there are barriers to adapting concepts of the GHS in the United States, there is considerable interest in the system and some activities related to its implementation. The four regulatory agencies potentially affected by the GHS are all actively engaged in considering adoption (EPA, U.S. Department of Transportation [DOT], OSHA, and Consumer Product Safety Commission [CPSC]). OSHA has prepared an analysis comparing the GHS to its HCS requirements, and in September 2006 published an advanced notice of proposed rulemaking to incorporate elements of the GHS into the HCS. Both the OSHA analysis and advanced notice are available on the OSHA Web site with links to the official text of the GHS as well. GHS implementation has also been a subject of discussion in OSHA meetings with its North American Free Trade Agreement (NAFTA) partners on handling of hazardous substances, and the three countries (Canada, Mexico, United States) have exchanged information about implementation activities on a regular basis. There is also an existing U.S./EU pilot project to link the GHS with CB in order to implement the GHS seamlessly across the Atlantic with CB as an integral part of this process that seeks to control exposures related to the international distribution of chemical inventory. Information relating to this pilot project can be found at http://www.useuosh.org with many useful discussions and subtopics that are also linked to the concepts presented in this critique. In the Asia-Pacific Economic Cooperation (APEC), a goal of implementation by 2006 was established. The United States also participates in this trade-related organization.

The GHS is seen by international organizations as a significant tool to ensure the sound management of chemicals worldwide. The GHS provides the informational framework upon which comprehensive programs to address chemical safety and health can be based in countries that do not have the infrastructure to create such a system. The additional benefit of having the system updated and maintained by an international body, rather than by each individual country, is also significant in the context of global chemical safety and health. Thus, WHO, ILO, IPCS, OECD, and other international organizations continue to promote its adoption and implementation worldwide. The United Nations Institute for Training and Research (UNITAR) is also working with ILO to promote implementation through pilot projects in various countries as well as other capacity building activities. The United States is a partner in this work, having provided some funding to UNITAR to promote implementation of the GHS. The ability to use CB in countries that have adopted the GHS has already been recognized as a potentially powerful tool to achieve chemical control in economies in transition.

On a grander scale, efforts to implement the GHS also provide an opportunity to work with and cultivate multinational cooperation with private enterprise in investing time, experts, and financing for the necessary field implementation, validation, and development of long-term occupational safety and health management systems that will be essential for building sound CB strategies. It should be emphasized that the best CB product, including toolkits and toolboxes, will be one that is transcendent of borders for implementation, yet adaptable to the specific legal and socio-cultural features of the countries in which it will be applied.

2.4 Recognition of Specific Industries or Activities Where CB May be Adopted

The primary, initial focus for using existing toolkits is within small chemical manufacturing facilities and trades that use chemicals within their processes and procedures. This initial effort should be structured to allow comparisons based on utility for medium and large chemical industries. This effort has already begun with the testing of COSHH Essentials in comparison with existing personal monitoring exposure assessments in India. Beyond COSHH Essentials and the International Chemical Control Toolkit related risk assessments for chemical exposures, work could begin by focusing on point source emissions with known solutions databases such as the inclusion of attributable portions of the Silica Essentials within a construction toolbox that seeks to incorporate silica dust, wood dust, noise, safety, traumatic injuries, and other well-documented control solutions. NIOSH has initiated projects which are considering applications for a qualitative risk assessment and management (control banding) strategy and the development of task-specific hazard control guidance. Seven small business industries are already being targeted because of increased rates of illness and injury compared to general industry: pallet manufacturing; concrete products; industries; roofing, siding, and sheetmetal;

plumbing, heating and air conditioning; auto and home supply stores; eating establishments; and medical offices and clinics. Currently, additional activities are in place to evaluate CB use with glutaraldehyde in healthcare facilities, metal working fluids, and silica exposure potential across all trades.

2.5 Additional Applications of CB in Ergonomics, Noise, and Traumatic Injuries

Ergonomics is a promising area for adaptation and adoption of CB strategies. Additional research and development is required before the utility of CB strategies in noise and traumatic injuries can be evaluated.

2.5.1 CB for Ergonomics

Ergonomics hazards are an area where a CB strategy could provide practical solutions to physical agents that may cause musculoskeletal disorders in the workplace. Whereas chemical inventories and applications continue to expand, with many substances lacking data on toxicity, exposures characteristics, and potential adverse health impacts, ergonomics has a finite group of well-researched and defined risk factors and effective programs. For applications in this arena the CB strategy could promote the use of practical tools for assessing and reducing local risks, some of which have been derived from recent achievements in participatory ergonomics in developing countries. Participatory-based programs in developing countries support low cost improvements in small enterprises, such as Work Improvement in Neighborhood Development (WIND) which focuses on agriculture, Work Improvement in Small Enterprises (WISE) [Muchiri 1995], and Participation-Oriented Safety Improvement by Trade union InitiatiVE (POSITIVE). To tie these concepts together, an inter-country network has been formed to exchange positive experiences and collaborate in training trainers and developing training tools called Work Improvement Network in Asia (WIN-Asia), which can be accessed at http://www.win-asia.org.

A reduction in work-related musculoskeletal disorders (WMSDs) is essential to the improvement of occupational health in both industrialized and developing countries. Currently 40% of the world's occupational and work-related health costs are attributed to musculoskeletal diseases [Takala 1999]. With industrialization taking root in several developing countries, ergonomic interventions need to be adaptable in order to span several industries and work sectors. Ultimately, this will require a programmatic process that is low cost, easy to understand, and sensitive and adaptable to the social, cultural, and political considerations of each targeted industry. One part of this process is putting in place a permanent ergonomic infrastructure to train and disseminate information to the internal groups and organizations in need. Within the process of training, a combination of ergonomic hazard assessment tools should be presented. These tools, or toolkits in development, could include a brief manual that leads to checklists for direct use by managers and workers of small enterprises in a manner that puts into practice the ILO Ergonomic Checkpoints document published in 1996 and currently being revised and updated. Initial toolkit versions could be implemented and assessed according to the usefulness of the approaches recommended. Examples of industry and task specific guidance that could be developed include an agricultural ergonomics toolkit, a construction ergonomics toolkit, and a human/computer interaction toolkit [Zalk 2003]. Essential in this toolkit development strategy will be a follow-up mechanism to ensure that the newly trained individuals (infrastructure) would receive some expert guidance when employing their new skills. Finally, an economic evaluation of expected improvements should become an integral part of the process. This would help facilitate management's acceptance of the proposed ergonomic interventions, providing justification for control development to eliminate or mitigate the hazards with supporting business case models and simple cost/benefit analyses [Zalk 2003; Stewart et al. 2005].

2.5.2 CB for Noise

An example of the difficulties in applying the CB strategy to physical agents is in controlling exposures to noise. Unlike the above approaches for chemical risks and ergonomics, an appropriate delineation for control needs and effectiveness would require precise exposure measuring equipment. There are too many factors, almost all workplace and worker specific, beyond the current concept for simple toolkit related applications that render simplification impractical. The key field guideline that can be used is whether noise levels are approaching existing standards. This guideline, common in field practice, is whether normal conversation is understandable at an approximate 2- to 3-foot distance from the speaker. If a person's voice needs to be raised for communication, then the noise exposure level is most likely at or above a key 85 dBA threshold. Above this threshold, the use of hearing protection for affected workers is advised. Any further recommendations above this level are directly tied to 3 dB (ACGIH TLV) or 5 dB (OSHA PEL) exchange rates that halve the time of exposure with each elevation of exchange rate. This precision would be difficult at best, and truly impractical in concept, to offer appropriate worker exposure times.

2.5.3 CB for Traumatic Injuries

In the year 2005, the U.S. Bureau of Labor Statistics reported almost 5,734 fatal occupational injuries (http://stats.bls.gov/iif/oshwc/cfoi/cfoi_revised05.htm). Within these injury statistics there are specific industries and activities associated with higher rates of injuries (both fatal and nonfatal). An example of this is in the manufactured wood pallet industry which has an overall increase of 245% in injury rates compared to general industry including >1,300% increase in amputations and >800% increase in cuts and punctures. Many industrial sectors (agriculture, construction) with hazards (confined spaces, electrical hazards, fall hazards) that contribute to occupational injuries could benefit from control-focused solutions and guidance. Traumatic injuries can be addressed within a construction toolbox through task-specific hazard guidance provided in training and included as control solutions. In addition, control solutions and guidance developed for one industry sector (e.g., construction) often have relevance to other industries, such as agriculture and mining, and can be applied to address similar hazards.

2.6 Determination of Potential Partnerships

Collaboration with multiple stakeholders, including national and international agencies, organized labor, trade groups, academic institutions, and professional societies can build capacity and maximize resources, contributing to improved toolkits to protect worker health globally.

The interest in CB strategies has grown and led to improvements based on partnerships to explore its utility for multiple applications and a variety of workplace settings. One organization instrumental in bringing forth the modern incarnation of CB is the IOHA, which is comprised of the established IH organizations worldwide. The concept is currently housed for international development within the WHOCC 2001–2005 Work Plan under Task Force 10; Preventive Technologies (http://www.who.int/occupational_health/en). The WHOCC is a collective effort that also maximizes partnerships with 70 Collaborating Centres around the globe working in concert with the ILO and the major occupational health Non-Governmental Organizations (NGOs) of IOHA, the International Commission on Occupational Health (ICOH), and the International Ergonomics Association (IEA). With the CB strategy having strong support within the development and dissemination protocol of the GHS discussed in this document, it is also intricately tied to the WHO/ILO IPCS office. It is under the auspices of the IPCS that an ITG has been established to facilitate the further development and implementation of the greater encompassing ORM Toolbox. ITG has recently developed a Global Implementation Strategy (see Appendix C) to ensure that national CB Work Plans are developed and implemented by relevant stakeholders. In addition to the multiple organizations discussed above, ITG is also partnering with the UK HSE, NIOSH, and the GTZ.

Building upon international coordination efforts of the ITG and its Global Implementation Plan, NIOSH and other organizations within the United States have initiated activities to explore CB options, research needs, and potential applications. The first effort to create greater awareness of this concept involved planning and coordination of the 2nd International Control Banding Workshop in Cincinnati, Ohio. Although international in concept, this workshop was supported by an essential U.S. partnership matrix including ACGIH, AIHA, OSHA, NIOSH, and NSC, in addition to the above global organizations of ILO, IOHA, and WHO. In fact, the current ITG Global Implementation Plan was initially drafted at this workshop. An outcome of this event was the need to consider U.S. specific parameters for developing a national CB effort. This led to the NCBW held in March 2005, in Washington, D.C. For this event, the U.S. partnership matrix was expanded to include representatives from the EPA, trade unions, corporations, and academia. These partnerships have been utilized for continued discussion and consideration of CB strategies, in cooperative efforts to address research needs, barriers to implementation, validation concerns, and create awareness of control-focused solutions and guidance.

3 DISCUSSION AND CONCLUSIONS

CB cannot address all occupational hazards. Despite this, CB strategies can be effectively utilized for performing workplace risk assessments and implementing control solutions for many occupational hazards. COSHH Essentials is a popular toolkit model that has been well researched, although further validation is important, with narrowed applications in the larger scale of CB. CB strategies will not eliminate the need for personal monitoring and should lead to an increased need for IH expertise and useful solution-based databases.

A review of the literature and the brief history of CB evolution, applications, and evaluation indicates that CB strategies cannot provide appropriate solutions for the assessment and management of all occupational hazards. There are situations in which CB cannot provide the precision and accuracy necessary to protect worker health; alternatively, there are undoubtedly situations in which CB will provide a higher level of control than is necessary. Despite these limitations, CB strategies have the potential to be entry level tools for occupational risk management. They can be an integral part of a tiered approach to risk assessment, in which simpler tools are used at a screening level, followed by a more complex approach as the need arises or is indicated by the particular situation [Nelson et al. 2003; Mulhausen et al. 2004].

The COSHH Essentials approach from the UK HSE was designed to help SMEs perform risk assessments for all chemicals and mixtures of chemicals indicated under the COSHH Regulations. The United States does not have any similar regulation that requires risk assessments for all chemicals in use. However, the basic premise is of value to industries in the United States—thousands of chemicals are in use and only a few levels of risk management (control bands) are available to control worker exposures to these chemicals. As an underlying principle, the COSHH Essentials is a valuable toolkit for CB strategies because it meets all six of

Money's [Money 2003] core principles (understandability, availability, practicality, user-friendliness, confidence on the part of users, and transparent, consistent output). The COSHH Essentials model must be viewed as a supplemental tool in a comprehensive program which also considers personal protection, training, and health surveillance, and not an unconditional replacement for a comprehensive risk management program [Oldershaw 2003].

In addition, the process of applying R-phrases to hazard bands is a useful practice, but is not intended to replace OELs [Brooke 1998]. With regard to applications of the CB model, Russell et al. [1998] point out that when performing risk assessments, employers should still consider other factors such as the need for health surveillance and the need to monitor exposure to ensure adequacy of control. Similarly, employers will want to consider recommending controls appropriate for the processes within their particular workplace. CB models ideally have utility in providing guidance for performing risk assessments and in selecting appropriate control measures, and not as a replacement for the traditional exposure monitoring and use of OELS.

As described previously, the validity of the exposure assessment component is essential to the effectiveness of the CB approach. An additional critical component is the establishment of a uniform and standardized toxicological characterization for a chemical by the supplier, using either R-phrases or similarly recognized categorical designations. It is the R-phrases that are applied to a substance or chemical mixture that determine its allocation to a hazard band and thus the intended target airborne concentration range. A continuing concern with most CB strategies, including COSHH Essentials, is the fact that they are primarily focused on the inhalation route of exposure. Consideration of other potential routes of exposure and anticipated toxicological endpoints could strengthen the utility of CB strategies and broaden the scope for recommending control options [Brooke 1998]. Further development of CB models should also consider procedures for ensuring adequate margins of safety and a schedule for frequent updates of information as it becomes available.

One potential benefit of CB implementation could be increased use of exposure assessment applications for field practice, providing additional information for surveillance of exposures and control effectiveness. As a consequence, the CB strategy could also have the effect of raising the profile of the industrial hygienist as an integral part of the workforce while maximizing the public health system for the benefit of the profession and the population at large. As part of the CB validation strategy, increased practice of exposure assessment will serve as the basis for evaluation of implemented controls, and will provide the feedback to improve the hazard control guidance information for subsequent revisions of the given toolkit.

4 RECOMMENDATIONS

Recommendations to facilitate the implementation of CB strategies in the United States are made under the categories of improving awareness of concepts, validation considerations, expansion of the CB model, dissemination, and coordination and collaboration.

4.1 Implementation of the Model in the United States

Drawing from the review of the literature and recent workshops, symposia, and conferences exploring the utility and potential applications of qualitative risk assessment and management (control banding) strategies, including the 2005 NCBW, the following recommendations have been identified with potential activities and programs to facilitate the implementation of CB in the United States.

4.1.1 Recommendations for Improving awareness and standardization of concepts

1. Coordinate terminology to ensure a singular CB vocabulary is established, adopted, understood, and communicated for practical purposes such as training, professional discussions, and application of concepts.
2. Carefully consider the exposure scenarios under which personal monitoring should be required as necessary following application of CB strategies, using specific R-phrases or more protective control bands to indicate such.
3. Adopt the GHS to work toward ensuring standardized hazard statements are available on U.S. chemical labels and safety data sheets to promote widespread CB applications. Include a procedure for frequent updates of information. Educate the wider occupational and environmental safety and health community on this change.

4. Develop a resource so that SME audiences can obtain additional assistance on implementing more protective control measures. Perhaps the CGSs could include a link to professional associations (AIHA, ACGIH), accredited labs and services, or provide a link to expert lists (accredited labs, consultants).
5. Continue to develop and offer training for professionals and for SME operators on the implementation of CB strategies and the Toolkit and Toolbox models available. Emphasize the role of CB in the context of tiered risk assessment, i.e., selection of the appropriate tool for a specific risk scenario.
6. Develop an incentive system based on input from broader groups of stakeholders including insurance, financial, trade, and legal interests.
7. Conduct research on the utility of CB to SMEs and the barriers to using it.

Recommendations for Validation

1. Make sure that a validation protocol considers the effectiveness of a given toolkit and its controls.
2. Use validation protocols to validate and compare various implementation methods and the construct in which they are introduced to both employers and workers.
3. Validate each step of the CB strategy independently: exposure prediction, hazard prediction, control recommendations, training, and control implementation.
4. Assess errors associated with CB hazard classification, exposure assessment, and control recommendations to determine the accuracy of the model.

4.1.3 Recommendations for Expanding the CB model

1. Develop a comprehensive, easy-to-use set of ergonomic hazard and risk assessment tools. These ergonomics toolkits should begin with a brief manual leading to checklists for use by SME employers and workers.
2. Consider dermal absorption as a factor which might impact hazard classification, exposure assessment, and control solutions in a CB risk management model.
3. Include guidance and control-focused solutions for additional substances, specifically those that were excluded by the UK HSE because they were regulated under other codes (e.g., pesticides, lead, silica).
4. Include processes that address combined chemicals use, mixtures, and compounds of variable composition that can have additive or synergistic safety and health consequences.

4.1.4 Recommendations for Disseminating CB

1. Develop public sector (governmental) and private sector (trade association, industry, organized labor, academic consortia) strategies to coordinate efforts for developing, implementing, and evaluating qualitative risk assessment and risk management approaches and task specific hazard control guidance.
2. Create awareness, implementation, and dissemination strategies among the regulatory, consultative, professional, and trade associations consistent with research to practice concepts.
3. Identify approaches for promoting the value and utility of CB using business case models and examples of broader workplace protections despite limited resources.

4.1.5 Recommendations for Coordination and Collaboration

National Coordination and Collaboration

1. Encourage NIOSH and OSHA cooperation in focusing on CB utility for special emphasis areas, such as hazard communication and guidance for small businesses. The State OSHA plans, fitting within the OSHA Alliance, may provide mechanisms to implement CB applications and demonstration projects for control-focused solutions and guidance.
2. Develop task-based CB toolkits that focus on point source exposures related to specific tasks and controls that have been validated. Where historical data exist to characterize exposure of a particular task (e.g., silica in mining or construction), hazard control guidance can be developed and provided in a practical, applicable format.
3. Include worker involvement as part of a tripartite approach within a participatory process for any implemented CB strategy. Provide for assessment and feedback for this process utilizing medical surveillance, with risk assessment based on health measures.
4. Coordinate resources and curricula for training professionals and SME audiences on the implementation of CB strategies and models available.

International Coordination and Collaborations

1. Coordinate the development and creation of an integrated system for both national and international databases. This database system should also include a component that tracks voluntary submission of data for the validation of various toolkits.
2. Adopt the ITG implementation strategy to coordinate occupational risk management concepts with international collaborative efforts, such as those within the WHOCC, in order to harmonize efforts and build capacity.

3. Link the CB strategies to an existing system of Occupational Safety and Health Management Systems for implementation. This will help to ensure it is maintained and improved within a management system that can be assessed at appropriate intervals and modified as necessary.

REFERENCES

ABPI [1995]. Guidance on setting in-house occupational exposure limits for airborne therapeutic substances and their intermediates. London: The Association of the British Pharmaceutical Industry.

Adelmann K [2001]. Chemical Safety and Development. Deutsche Gesellschaft fur Technische Zusammenarabeit [GTZ]: 10 pp.

ACGIH [2007]. About – History. http://www.acgih.org/about/history.htm . Updated 05/15/2007.

AIChE [1992]. Guidelines for hazard evaluation procedures, 2nd ed. New York: American Institute of Chemical Engineers.

AIChE [1994]. Dow's fire and explosion index hazard classification guide. New York: American Institute of Chemical Engineers.

Anfilogoff M [2004]. Personal communication from Mark Anfilogoff, Department of U.K. Trade and Industry, Small Business Service, March.

Aw TC [1989]. Control of substances hazardous to health. BMJ *299*(6705):931–932.

Balsat A, de Graeve J, Mairiaux P [2003]. A structured strategy for assessing chemical risks, suitable for small- and medium-sized enterprises. Ann Occup Hyg *47*(7):549–556.

Balsat A, Mairiaux P, DeGraeve J [2002]. A global approach for assessing and managing chemical risks at the workplace: advantages, limits and perspectives. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Balsat A, Mairiaux P, et al. [2002]. REGETOX 2000: A global approach for assessing and managing chemical risks at the workplace: Advantages, limits and perspectives. 1st International Workshop on Control Banding. London, England. 4–5 November 2002.

Barker J P, Abdelatti MO [1997]. Anaesthetic pollution. Potential sources, their identification and control. Anaesthesia *52*(11):1077–1083.

Brooke IM [1998]. A UK scheme to help small firms control health risks from chemicals: toxicological considerations. Ann Occup Hyg *42*(6):377–390.

Burstyn I, Teschke K [1999]. Studying the determinants of exposure: A review of methods. Am Ind Hyg Assoc J *60*:57–72.

Burton DJ [2004]. Industrial hygiene in decline—What can we do? Donald E. Cummings Memorial Award Lecture. J Occup Environ Hyg *1*(12).

Cherrie J, Schneider T [1999]. Validation of a new method for structured subjective assessment of past concentrations. Ann Occup Hyg *43*(4):235–245.

CFR. Code of Federal regulations. Washington, DC: U.S. Government Printing Office, Office of the Federal Register.

CIA [1992]. Safe handling of potentially carcinogenic aromatic amines and nitro-compounds. London: Chemical Industries Association.

CIA [1993]. Safe handling of colourants 2: hazard classification and selection of occupational hygiene strategies. London: Chemical Industries Association.

CIA [1997]. The control of substances hazardous to health regulations (COSHH): guidance on allocating occupational exposure bands (Regulation 7). London: Chemical Industries Association.

Cooke RA, Gavaghan S, et al. [1991]. General practitioners' awareness of COSHH regulations. BMJ *303*(6810):1132.

Crabtree HC, Hart D, et al. [1991]. Carcinogenic ranking of aromatic amine and nitro compounds. Mutation Res *264*:155–162.

Donoghue AM [2004]. Occupational health hazards in mining: an overview. Occup Med *54*(5):283–289.

EASHW [2005]. Good practice for small and medium enterprises. European Agency for Safety and Health at Work. Available at http://sme.osha.eu.int/good_practices/index_en.htm, accessed 24 February 2005.

EC [1998]. European Commission. Council Directive 98/24/EC on the protection of the health and safety of workers from risks related to chemical agents at work. Off J Eur Commun; L131.

EC [2001]. European Commission. White paper on the strategy for a future chemicals policy, document COM [2001] 88. Brussels: European Commission.

EC [2004]. EC Fifth Framework Programme. RISKOFDERM: Risk assessment for occupational dermal exposure to chemicals. RTD Project QLK40CT-1999-01107.

ECETOC [2002]. European Centre for Ecotoxicology and Toxicology of Chemicals. Outline concept of a pragmatic approach to risk assessment. Brussels: ECETOC. http://www.ecetoc.org.

EEC [1967]. Council Directive 67/548/EEC of 27 June 1967. Available at http://ecb.jrc.it/Legislation/1967L0548EC.htm.

EEC [1987]. European Economic Community. Legislation on Dangerous Substances: Classification and Labelling in the European Communities: Consolidated Text of Council Directive 67/548/EEC. Vols. 1–2, Graham and Trotman Ltd, London, UK.

EINECS [1987]. European inventory of existing commercial chemical substances, Vols. I–VIII. Commission of the European Communities, EEC, Brussels, Belgium.

Ennals R [2002]. Partnership for Sustainable Healthy Workplaces: Warner Lecture, BOHS, Sheffield, 9 April 2002. Ann. Occup. Hyg. *46*:423–428.

Fairhurst S [2002]. Toxicology. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Falconer K [2002]. Pesticide environmental indicators and environmental policy. J Environ Manage 65(3):285–300.

Flynn MR, Susi P [2003]. Engineering controls for selected silica and dust exposures in the construction industry—a review. Appl Occup Environ Hyg *18*(4):268–277.

Fraise AP [1999]. Choosing disinfectants. J Hosp Infect *43*(4):255–264.

Gardiner K [2002]. The "usefulness" of the control banding approach for countries in transition: South Africa and Thailand. Presented at the First International Control Banding Workshop, London, 4-5 November 2003.

Gardner RJ, Oldershaw PJ [1991]. Development of pragmatic exposure-control concentrations based on packaging regulation risk phrases. Ann Occup Hyg *35*(1):51–59.

Garrod AN, Rajan-Sithamparanadarajah R [2003]. Developing COSHH Essentials: dermal exposure, personal protective equipment and first aid. Ann Occup Hyg *47(7)*:577–588.

Garrod A, Rajan-Sithamparanadarajah B, et al. [2004]. COSHH Essentials: technical developments. Presented at the Second International Control Banding Workshop: Validation and Effectiveness of Control Banding. 1-2 March 2004, Cincinnati, OH.

Goede HA, Tijssen SC, Schipper HJ, Warren N, Oppl R, Kalberlah F, VanHemmen JJ [2003]. Classification of dermal exposure modifiers and assignment of values for a risk assessment toolkit. Ann Occup Hyg *47(*8):609–618.

Goldsmith DF [1997]. The link between silica dust levels, risk assessments, and regulations. J Expo Anal Environ Epidemiol. Jul-Sep;7[3]:385-95. J Expo Anal Environ Epidemiol 7[3]: 385-95.

Guest I [1998]. The Chemical Industries Association guidance on allocating occupational exposure bands. Ann Occup Hyg *42*(6):407–411.

Harrison DI [1991]. Control of substances hazardous to health [COSHH] regulations and hospital infection. J Hosp Infect 18 Suppl A: 530-4.

Harrison J, Sepai O [2000]. Should control measures be based on air measurements or biological/biological effect monitoring? Occup Med [Lond] 50[1]: 61-3.

Henneberger, P. K., K. Kreiss, et al. [1999]. An evaluation of the incidence of work-related asthma in the United States. International Journal of Occupational and Environmental Health 5[1 [Jan-Mar]]: 1-8.

Henry BJ, Schaper KL [1990]. PPG's safety and health index system: a 10-year update of an in-plant hazardous materials identification system and its relationship to finished product labeling, industrial hygiene, and medical programs. Am Ind Hyg Assoc J *51:*475–484.

HMSO [1988]. The control of substances hazardous to health regulations 1988 (Statutory Instrument 1657). London: Her Majesty's Stationery Office. HMSO.

HMSO [2002, 1999]. Statutory Instrument [SI] 2002/2677 and 1999/437, The Control of Substances Hazardous to Health (COSHH) Regulations. Stationary Office 2002 ISBN 0 11 042919 2.

Howard J [2004]. Opening Speech, Second International Control Banding Workshop, Cincinnati, OH, 1-2 March 2004.

HSE [1999]. COSHH Essentials—easy steps to control chemicals. Sudbury: UK Health and Safety Executive. HSE Books. http://www.coshh-essentials.org.uk/.

HSE [2000]. Control of chemicals in printing: COSHH essentials for printers. London: HSE. UK Health and Safety Executive.

HSE [2001]. Asbestos Essentials Task Manual: Task guidance sheets for the building maintenance and allied trades.

HSE [2002]. COSHH, 4th ed. Approved Code of Practice and Guidance. Sudbury: HSE Books. UK Health and Safety Executive.

HSE [2002a]. Control of substances hazardous to health, 4th ed. The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance.

Hudspith B, Hay AW[1998]. Information needs of workers. Ann Occup Hyg *42*(6):401–406.

Hutt G [1994]. Glutaraldehyde revisited. Br J Theatre Nurs *3*(10):10–11.

ICE [1985]. The assessment and control of hazards. Rugby: Institute of Chemical Engineers.

Jackson H [2002]. Control Banding—Practical tools for controlling exposure to chemicals. Asian-Pacific Newsletter 9:62–63.

Jackson H, Vickers C [2003]. Report of the International Control Banding Workshop, London, November 2002. http://www.ioha.com/topics/control_banding/cbwupdate.pdf.

Jayjock MA, Lynch JR, Nelson DI [2000]. Risk assessment principles for the industrial hygienist. AIHA Press, Fairfax, VA.

Jones R, Nicas M [2004]. Evaluation of the ILO Toolkit with regards to hazard classification and control effectiveness. Poster presented at the 2nd International Control Banding Workshop, 1-2 March 2004, Cincinnati, OH.

Jones R, Nicas M [2006a]. Evaluation of COSHH essentials for vapor degreasing and bag filling operations. Ann Occup Hyg *50*(2):137–147.

Jones R, Nicas M [2006b]. Margins of safety provided by COSHH Essentials and the ILO Chemical Control Toolkit. Ann Occup Hyg *50*(2):149–156.

Kalisz S [2000]. Safety beyond OSHA requirements. Occup. Health Saf. *69*(3):66–67.

Kirkwood P, Trenchard PJ, Uzel aR, Colby PJ [1991]. SARAH: an expert system for training non-hygienists in carrying out occupational hygiene assessments. Ann Occup Hyg *35*(2):233–237.

Kolanz M, Madl A, et al. [2001]. A comparison and critique of historical and current exposure assessment methods for beryllium: implications for evaluating risk of chronic beryllium disease. Appl Occup Environ Hyg 16(5):593–614.

Kromhout H [2002a]. Design of measurement strategies for workplace exposures. Occup Environ Med *59*(5):349–354.

Kromhout H [2002b]. Design of measurement strategies for workplace exposures [letter to the editor]. Occup Environ Med *59*:788–789.

Lewis DJ [1980]. The Mond fire, explosion and toxicity index. In: Proceedings of the 15th annual loss prevention symposium. New York: AIChE.

Loughney E, Harrison J [1998]. Irritant contact dermatitis due to 1-bromo-3-chloro-5,5-dimethylhydantoin in a hydrotherapy pool. Risk assessments: the need for continuous evidence-based assessments. Occup Med *48*(7):461–463.

Maidment SC [1998]. Occupational hygiene considerations in the development of a structured approach to select chemical control strategies. Ann Occup Hyg *42*(6):391–400.

Marquart J, Brouwer DH, Gijsbers JHJ, Links IHM, Warren N, VanHemmen JJ [2003]. Determinants of dermal exposure relevant for exposure modelling in regulatory risk assessment. Ann Occup Hyg *47*(8):599–607.

Menzies D [1995]. Glutaraldehyde—controlling the risk to health. Br J Theatre Nurs *4*(11):13, 15.

Molyneux,MK, Wilson HGE [1990]. An organized approach to the control of hazards to health at work. Ann Occup Hyg *34*(2):177–188.

Money CD [1992a]. The use of generic risk assessment in the harmonization of workplace standards in the pharmaceutical industry.

Money CD [1992b]. A structured approach to occupational hygiene in the design and operation of fine chemical plant. Ann Occup Hyg *36*(6):601–607.

Money CD [2001a]. Data solutions for the 21st century: CEFIC's vision and intentions. Appl Occup Environ Hyg *16*(2):329–330.

Money CD [2001b]. The European chemical industry's needs and expectations for workplace exposure data. Appl Occup Environ Hyg *16(*2):300–303.

Money CD [2002a]. Invited Editorial. European chemical regulation and occupational hygiene. Ann Occup Hyg *46*(3):275–277.

Money CD, Margary SA [2002b]. Improved use of workplace exposure data in the regulatory risk assessment of chemicals within Europe. Ann Occup Hyg 46(3):279-285.

Money CD[2003]. European experiences in the development of approaches for the successful control of workplace health risks. Ann Occup Hyg *47*(7):533–540.

Muchiri F [1995]. Workplace improvements achieved by the WISE [Work Improvements in Small Enterprises] methodology in Africa. Document from the Directorate of Occupational Health and Safety Services. P.O. Box 34120, Nairobi, Kenya.

Mulhausen J, Logan P, et al. [2004]. Integrating control banding into the AIHA Exposure Assessment Strategy model, presented at the Second International Control Banding Workshop, Cincinnati OH, March 2004.

Naumann BD, Sargent EV [1997]. Setting occupational exposure limits for pharmaceuticals. Occup Med *12*(1)]:67–80.

Naumann BD, Sargent EV, Starkman BS, Fraser WJ, Becker GT, Kirk GD [1996]. Performance-based exposure control limits for pharmaceutical active ingredients. Am Ind Hyg Assoc J *57*(1):33–42.

Nelson DI, Mirer F, et al. [2003]. Risk Assessment in the Workplace. Chapter 9. Dinardi SR, ed. The Occupational Environment: Its Evaluation, Control, and Management, 2nd ed. Fairfax, VA: AIHA.

Nelson DI, Zalk DM [2004a]. Report from the 2nd International Control Banding Workshop. The Global Occupational Health Network [GOHNET][7].

Nelson DI, Zalk DM [2004b]. Control Banding: Wish I'd thought of it myself! AIH Diplomate 04[3]: v–vii.

Nighswonger T [2001]. How can Industrial Hygienists position themselves for success? Occup Hazards 57:3095.

NIOSH [1999]. Identifying High-Risk Small Business Industries, The Basis for Preventing Occupational, Injury, Illness, and Fatality. Cincinnati, OH: U.S. Deparatment of Health and Human Services, Public Health Service, Centers for Disease and

Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 99–107. Available at http://www.cdc.gov/niosh/sbintro.html].

NIOSH [2002]. Worker Health Chartbook 2000, May 2002 revision. Available at http://www.cdc.gov/niosh/00-127pd.html, accessed 02/06/08.

NIOSH [2004]. Worker Health Chartbook 2004. Available at http://www.cdc.gov/niosh/docs/chartbook/, accessed 02/06/08.

Northage C, Marquart H [2001]. Occupational exposure information needs for regulatory risk assessment of existing chemicals. App Occup Environ Hyg *16*(2):315–318.

Ogden T [1998]. The sunset of exposure limits—and the dawn of something better (editorial)? Ann Occup Hyg *42*(6):355–356.

Oldershaw P [2002]. Control banding: an overview. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Oldershaw PJ [2003]. Control banding workshop, 4-5 November 2002, London. Ann Occup Hyg *47*(7):31–32.

Oldershaw P, Fairhurst S [2001]. Sharing toxicological information on industrial chemicals. Ann Occup Hyg *45*(4):291–294.

Oppl R, Kalberlah F, Evans PG, VanHemmen JJ [2003]. A toolkit for dermal risk assessment and management: an overview. Ann Occup Hyg *47*(8):629–640.

Palmer KT, Freegard J [1996]. Compliance with the Control of Substances Hazardous to Health Regulations [COSHH] 1988 and health and safety awareness in hairdressing establishments. Occup Med *46*(1):49–52.

Parker SE [1989]. Use and abuse of volatile substances in industry. Hum Toxicol *8*(4): 271–275.

Rappaport SM, Goldberg M, et al. [2003]. Excessive Exposure to Silica in the US Construction Industry. Ann Occup Hyg *47*:111–122.

RSC [2003]. COSHH in laboratories, 2nd ed. London: Royal Society of Chemistry.

Ruden C, Hansson SO [2003]. How accurate are the European Union's classifications of chemical substances. Toxicol Lett *144*(2):159–172.

Russell RM, Maidment SC, Brooke I, Topping MD [1998]. An introduction to a UK scheme to help small firms control health risks from chemicals. Ann Occup Hyg *42*(6):367–376.

Scholaen S [2003]. Pilot Project Chemical Safety. PowerPoint slide presentation, 13.02.2003, IPCS, Geneva.

Scholaen S [2004]. Application of chemical management and control strategies in small- and medium-sized companies in Indonesia. Presented at the Second International Control Banding Workshop: Validation and Effectiveness of Control Banding. 1-2 March 2004, Cincinnati, OH.

Schuhmacher-Wolz U, Kalberlah F, Oppl R, VanHemmen JJ [2003]. A toolkit for dermal risk assessment: toxicological approach for hazard characterization. Ann Occup Hyg *47*(8):641–652.

Schulte PA, Lentz TJ, et al. [2004]. Knowledge Management Appraisal of Occupational Hygiene in the United States. Ann Occup Hyg *48*(7):583–594.

Seaton A [1989]. Control of substances hazardous to health: far reaching legislation or dead letter? BMJ *298*:846–847.

Stewart K, Kiefer M, et al. [2005]. Establishing Ergonomics in Industrially Developing Countries. Proceedings, International Occupational Hygiene Triennial Scientific Conference, South Africa. Proceedings pending.

Swuste P [2002]. Occupational hazards, risk, and solutions. Presented at the First International Control Banding Workshop, London, 4-5 November 2003.

Swuste P, Hale A [1994]. Databases on measures to prevent occupational exposure to toxic substances. Appl Occup Environ Hyg *9*(1):57–61.

Swuste P, Hale A, Pantry S [2003]. Solbase: a databank of solutions for occupational hazards and risks. Ann Occup Hyg *47*(7):541–547.

Tait K [2004]. Control banding: an improved means of assessing and managing health and safety risks at Pfizer. Presented at the Second International Control Banding Workshop: Validation and Effectiveness of Control Banding. 1–2 March 2004, Cincinnati, OH.

Takala J [1999]. Introductory report of the ILO, International Occupational Safety and Health Information Centre, Geneva, International Labour Office.

Tielemans E, Marquart H, et al. [2002]. A proposal for evaluation of exposure data. Ann Occup Hyg *46*(3):287–297.

Tijssen S, le Feber M, et al. [2004]. A new tool for small and medium enterprises to work safely with hazardous substances. Presented at the Second International Control Banding Workshop: Validation and Effectiveness of Control Banding. 1-2 March 2004, Cincinnati, OH.

Tischer M [2001a]. What does "low exposure" mean? Exposure considerations in the testing of notified new substances. Appl Occup Environ Hyg *16*(2):228–232.

Tischer M [2001b]. Helping SMEs to manage risks from chemicals in the workplace. Proceedings from an international workshop, 26-27 November 2001, Amsterdam, The Netherlands. Zeist: TNO Nutrition and Food Research.

Tischer M [2002]. Current BAuA/GTZ research on occupational exposure and control strategies: recent results from various industrial areas and from Indonesian SMEs. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Tischer M, Bredendiek-Kamper S, Poppek U [2003a]. Evaluation of the HSE COSHH Essentials exposure predictive model on the basis of BAuA field studies and existing substances exposure data. Ann Occup Hyg *47*(7):557–569.

Tischer M, Scholaen S [2003b]. Chemical management and control strategies: experiences from the GTZ pilot project on chemical safety in Indonesian small- and medium-sized enterprises. Ann Occup Hyg *47*(7):571–575.

Topping M [2001]. Occupational exposure limits for chemicals. Occup Environ Med *58*(2):138–144.

Topping M [2002]. Design of measurement strategies for workplace exposures: Letter to the editor. Occup Environ Med *59*:788.

Topping M [2002b]. COSHH Essentials: from concept to one stop system. Presented at the First International Control Banding Workshop, London, 4-5 November 2003.

Topping MD, Williams CR, Devine JM [1998]. Industry's perception and use of occupational exposure limits. Ann Occup Hyg *42*(6):357–366.

TRG [1996]. Technische Regeln fur Gefahrstoffe. Ermitteln und Beurteilen der Gefahrdungen durch Gefahrstoffe am Arbeitsplatz: Ermitteln von Gefahrstoffen und Methoden zuer Ersatzstoffprufung. TRGS 440. Berlin: Technische Regeln fur Gefahrstoffe.

UIC [1999]. Outil d'evaluation des risques lies aux produits chimiques, document technique DT 63. Paris:]. Union des Industries Chimiques.

van Hemmen JJ, Auffarth J, Evans PG, Rajan-Sithamparanadarajah B, Marquart H, Oppl R [2003]. RISKOFDERM: risk assessment of occupational dermal exposure to chemicals. An introduction to a series of papers on the development of a toolkit. Ann Occup Hyg *47*(8):595–598.

Van-Wendel-de-Joode B, Brouwer DH, Vermeulen R, VanHemmen JJ, Heederik D, Kromhout H [2003]. DREAM: a method for semi-quantitative dermal exposure assessment. Ann Occup Hyg *47*(1):71–87.

Vickers C, Fingerhut M [2002]. WHO/IPCS global effort on control banding. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Vincent R, Bonthoux F [2000]. Evaluation du risque chimique: Hierarchisation des risques potentials. INRS Cahiers de notes documentaires—Hygiene et securite du travail *179*:29–34.

Wagner G, Wegman D [1998]. Occupational asthma: Prevention by definition. American J Ind Med *33*:427–429.

Waldron HA [1989]. COSHH and the NHS. Br J Ind Med *46*(11):753–754.

Warren N, Goede HA, Tijssen SCHA, Oppl R, Schipper HJ,VanHemmen JJ [2003]. Deriving default dermal exposure values for use in a risk assessment toolkit for small and medium-sized enterprises. Ann Occup Hyg *47*(8):619–627.

Winterbottom JE [1987]. The control of substances hazardous to health regulations: an industrialist's view of legislation. Ann Occup Hyg *31*(1):81–88.

Woodward KN, McDonald A, Joshi S [1991]. Ranking of chemicals for carcinogenic potency—a comparative study of 13 carcinogenic chemicals and an examination of some of the issues involved. Carcinogenesis *12*(6):1061–1066.

Yap SM [2004]. Assessing the utility of the ILO Toolkit in Singapore. Presented at the Second International Control Banding Workshop: Validation and Effectiveness of Control Banding. 1–2 March 2004, Cincinnati, OH.

Zalk DM [2001]. Grassroots ergonomics: initiating an ergonomics program utilizing participatory techniques. AnnOccup Hyg *45*(4):283–289.

Zalk DM [2002a]. Participatory occupational hygiene; a path to practical solutions. Asian-Pacific Newsletter 9:51.

Zalk DM [2002b]. Control banding workshop closing session. Presented at the First International Control Banding Workshop, London, 4–5 November 2003.

Zalk DM [2003]. Control banding principles to reduce musculoskeletal disorders; the ergonomics toolkit. Proceedings of the International Ergonomics Association Triennial Congress, South Korea, V5[327].

APPENDIX A

RELATED PUBLICATIONS WITH SELECTED ANNOTATIONS

Falconer K [2002]. Pesticide environmental indicators and environmental policy. J Environ Manage *65*:285–300.

Falconer assesses the feasibility developing environmental banding for more effective pesticide policy, specifically the development of pesticide groupings. The groupings would focus on broad similarities and differences rather than precise individual ordering. However, due to the complexity of pesticides, their usage, and impacts, no single eco-toxicological parameter can be used to define and quantify policy issues. Falconer suggested hazard-based indicators rather than impact assessment, which must be conducted for each site. Enhanced pesticide labeling could be useful in decision-making by users. He concluded that pesticide groupings would be more feasible and useful than ranking of individual products.

Kirkwood P, Trenchard PJ, Uzel AR, Colby PJ [1991]. SARAH (System for Advising on the Regulations for Assessing Hazards): an expert system for training non-hygienists in carrying out occupational hygiene assessments. Ann Occup Hyg *35*:233–237.

Similar to COSHH Essentials, the SARAH expert system can ease the workload of occupational hygienists by providing nonexperts with the tools to solve simpler occupational safety and health problems. It was designed for use by British Gas to assist in meeting COSHH requirements.

Money CD [2002a]. European chemical regulation and occupational hygiene. Ann Occup Hyg *46*:275–277.

This document describes the drivers for risk assessment of chemicals in the EU:

- 400 million tonnes of chemicals produced globally in 2001
- 100,000 substances registered in the EU
- 10,000 chemicals marketed in volumes >10 tonnes, and 20,000 marketed at 1–10 tonnes.
- In 1998, chemicals were the third largest manufacturing industry, employing 1.7 million people directly
- Several leading multinationals and 36,000 SMEs were involved
- Known adverse human health effects of many chemicals, and lack of knowledge about the impacts of many chemicals

It also outlined the REACH system. There will be a tiered approach to registration, triggered by production volumes. This proposal would result in a central database where critical information about most chemicals would be registered [Money 2002a]. Higher anticipated risks would trigger higher levels of required information.

Northage C, Marquart H [2001]. Occupational exposure information needs for regulatory risk assessment of existing chemicals. Appl Occup Environ Hyg *16*:315–318

Describes the information required to conduct a risk assessment per EU Regulation 1488/99, which requires risk assessments to be conducted on priority existing chemicals, including human health and environmental concerns. These assessments are carried out at the national level. Data requirements for exposure assessment include the following:

- Description of work activities, percentage of substance in product, amounts used
- Distinction between different exposure scenarios
- Measurement methods
- Raw sampling data and statistical descriptors
- Task information
- Controls information
- Number of sites to which data apply
- Year
- Explanation of outliers
- Explanation of changes in exposures

Oldershaw P, Fairhurst S [2001]. Sharing toxicological information on industrial chemicals. Ann Occup Hyg 45:291–294.

Sound risk management and regulatory standards require complete toxicological data on a chemical. Some of the barriers to global access to robust toxicological profiles and related issues include shortage of data, conflicting positions on data interpretation, poor transfer of toxicological information, inefficiencies in the use of available resources, and inadequate understanding of the science. Indications of progress include increasing quantities of data (e.g., the International Council of Chemical Associations commitment to a *baseline* of data on the High Production Volume substances, harmonizing positions on data interpretation, better transfer of toxicological data to those exposed, more efficient use of available resources, and improved understanding of the science. Oldershaw and Fairhurst called for more international collaboration, assessment with an eye to international needs, better understanding on the part of users, clear establishment of the state of available knowledge, a pragmatic approach, agreement/codification/ expression of scientific terminology, and clear descriptions of extrapolation procedures.

Tischer M [2001a]. What does *low exposure* mean? Exposure considerations in the testing of notified new substances. Appl Occup Environ Hyg *16*:228–232.

Tischer suggested the use of R-phrases and the hazard banding model developed by the UK HSE to aid in decision-making on chemicals with no NOAEL during the EU notification procedures for new substances.

Zalk DM [2001]. Grassroots ergonomics: initiating an ergonomics program utilizing participatory techniques. Ann Occup Hyg *45*:283–289.

Zalk emphasizes the important role of worker participation in developing effective ergonomics programs, both in industrialized and newly industrializing nations. Such an approach could be very valuable in world-wide application of CB techniques.

APPENDIX B

ALLOCATION OF HAZARD BANDS FOR VAPORS

The evolution of the assignment of chemical R-phrases to the Hazard Bands A-E used in the COSHH Essentials has been explained [Brooke 1998]. Along with that explanation, the R-phrase assignments were compared to health-based OELs for a selection of chemical substances. Each hazard band, which is based on toxicological considerations, covers a log (10-fold) concentration range. As the relationship between the part per million (ppm) concentration of a vapor and the mg/m^3 concentration is a function of its molecular weight (and also temperature and pressure, though not discussed in this article), the working group who oversaw development of this chemical classification decided to adopt a pragmatic approach and to align the exposure bands. However, it must be noted that due to this alignment, "in mg/m^3 terms, the concentration range for substances in vapor form is substantially higher than that for the substance in particulate form, for the same toxicological hazard band. Classification of a substance is influenced by presence of an identifiable dose threshold, seriousness of the resultant health effect, and relative exposure level at which toxic effects occur. If a substance has more than one R-phrase, the R-phrase leading to the highest level of control governs.

Because of concern about the alignment procedure described by Brooke [1998], R-phrases for vapors are allocated based on additional considerations. For example, the classification of R48 indicates danger of serious damage to health by prolonged exposure. Exposure periods for animal inhalation toxicological studies are typically 6 hours. If severe effects occur at 0.025 to 0.25 mg/L for 6 hours of exposure during 90 days, the substance is rated R48/20 – Harmful. (0.025 mg/L represents the lower cut-off value;

severe effects at a lower concentration would result in a rating of R23 – Toxic.) Adjusting to a time period of 8 hours, and converting units, results in an equivalent 8-hour TWA of 19 to 190 mg/m^3. For three hypothetical vapors with molecular weights of 50, 100, and 150, the equivalent 8-hour airborne concentrations were converted from mg/m^3 to parts per million (ppm), for the lower (<19 mg/m^3), mid (19 – 190 mg/m^3), and upper (>190 mg/m^3) concentrations from the R48 range, resulting in a range of concentrations from 3 to 90 ppm. The resulting ppm concentrations were compared with the concentrations that would be experienced in Hazard B (>5–50 ppm). These comparisons showed in safety margins well below a value of 1.0 in the worst cases (generally involving high molecular weight compounds). Best-case comparisons, e.g., higher R48 cut-off values compared with the lower airborne concentrations for Hazard Band B (associated with lower molecular weight compounds), resulted in safety margins ranging up to 18.

The results of this analysis, which indicated that allocating Hazard B for vapors could result in significant concern for potential health effects under worst-case scenarios, led to the allocation of R48/20 to Hazard Band C. A similar analysis for dusts indicated higher margins of safety for dusts than for vapors, under similar assumptions, and resulted in an even greater safety factor for dusts than for vapors. This logic was extended to Toxic substances based also on repeated exposures, assigning them to Hazard Band D. Similar logic resulted in the assignment of compounds to hazard bands based on effects resulting from single exposures (Harmful to Band B, Toxic to Band C, and Very Toxic to Band D).

For compounds with no identifiable dose threshold and potentially serious health effects, e.g., R40 Muta. Cat. 3, R46 Muta. Cat 1 or 2, and R42 (respiratory sensitization), the appropriate allocation was Hazard Band E, which is always referred to expert advice. R-phrases for reproductive toxicity and carcinogens with nongenotoxic mechanisms and identifiable thresholds were allocated to Hazard Band D. Category 3 carcinogens with genotoxic mechanisms were put in Hazard Band E, as were Category 1 or 2 carcinogens, based on the EU Carcinogens Directive. Substances with corrosive or severe irritant effects, and skin sensitizers, were assigned to Hazard Band C, based on their identifiable threshold. Moderate eye and skin irritants were assigned to Hazard Band A.

It must be stressed that substances should only be assigned to Hazard Band A after full consideration of toxicological data indicates such, and not because of a lack of data.

APPENDIX C

GLOBAL IMPLEMENTATION STRATEGY

OCCUPATIONAL RISK MANAGEMENT TOOLBOX

GLOBAL IMPLEMENTATION STRATEGY

(Agreed by the IPCS International Technical Group on May 28, 2004)

Introduction

This Global Implementation Strategy aims to build and implement an Occupational Risk Management Toolbox (Toolbox), containing toolkits to manage different workplace hazards. The first such toolkit, the International Chemical Control Toolkit (Chemical Toolkit), is based on an approach to risk assessment and management called control banding (CB). This approach groups workplace risks into control bands based on combinations of hazard and exposure information. It can also be applied to non-chemical workplace hazards. As this banding technique is semi-quantitative or qualitative depending on the application, it is particularly relevant for use in small and medium-sized enterprises, developing nations, and, in the case of chemicals, where no occupational exposure standard has been set. It may also be useful for environmental risk assessment and management, as health and environment controls are complementary, and often inseparable, at the workplace level.

Aim of the Global Implementation Strategy and Implementation Partners

Under the auspices of the International Programme on Chemical Safety (IPCS), an International Technical Group (ITG) has been established to facilitate the further development and implementation of the Toolbox. This Global Implementation Strategy provides key high-level approaches to achieve this aim. It is intended that workplans, focusing on particular applications, countries or regions, would be developed and implemented by relevant stakeholders. A particular focus of this Strategy is implementation of the Chemical Toolkit.

Partners in this international effort include: IPCS (International Labour Organization and World Health Organization); International Occupational Hygiene Association (IOHA); The Health and Safety Executive (HSE) in Great Britain; US National Institute for Occupational Safety and Health (NIOSH); and the German Gesellschaft für Technische Zusammenarbeit (GTZ). As this Strategy is implemented, new partnerships will be encouraged. The ITG Terms of Reference and Membership List are provided in Annex 1, which will be updated as needed.

Stakeholders

Stakeholders include implementers (including employers), researchers and workers/users of chemicals. Bodies that may be involved in the implementation of this Strategy include: intergovernmental and international non-governmental organizations (such as IOHA); government agencies; industry, including associations of chemical producers and suppliers; employer and employee associations; industrial hygienists; labour unions; labour inspectors; researchers; and training professionals.

The International Chemical Control Toolkit

The Chemical Toolkit (adapted from the HSE's COSHH Essentials) is available on the internet through the ILO SafeWork Website. It is undergoing further development, which will include technical improvement and additions. This process will also include translation and piloting in selected countries. The hazard information employed by the Toolkit is either the European Union (EU) label Risk (R) phrases, or the hazard statements of the Globally Harmonized System for Classification and Labelling (GHS). The target for global implementation of the GHS is 2008, individual country implementation dates could vary. Hence implementation of the Chemical

Toolkit will need to be phased, initially focusing on building the necessary skills, knowledge and mechanisms for implementation, development and testing of guidance sheets, translation into other languages, and application of more generic approaches, such as the GTZ Chemical Management Guide (which is based on a simplified control banding technique). Implementation of the full Chemical Toolkit will be dependent on that country's use of EU risk phrases and/or GHS hazard statements.

Key Elements of the Implementation Strategy

Key elements are listed below, with lead bodies in parenthesis where relevant. At the workplan level, detailed actions taken must take into account the different needs of developing countries, economies in transition and developed countries. However harmonized approaches should be used where possible to avoid unnecessary duplication of effort.

1. Further develop the Chemical Toolkit, including the following:
   - Development of new control guidance sheets based on experience, to meet the needs of developing countries in particular (ILO with the input of others including GTZ; IOHA). This includes piloting, testing, evaluation and revision. The need for country-specific sheets will be explored. However, unnecessary differences in the technical materials should be avoided. Some guidance sheets should be trade and/or task specific.
   - As guidance sheets begin to be developed by implementers (e.g. country-specific sheets), a mechanism for peer review, including peer review criteria will be developed and the guidance sheets shared through an international Clearing House (see below) (ILO, WHO).
   - Development of sheets for workplace processes that generate chemical exposures (ILO, IOHA).

- Addition of the skin route of exposure (the Chemical Toolkit currently focuses on inhalation exposure) (ILO with the input of HSE).
- Translation in local languages (WHO CC, ILO, others).

2. Enhance links between the GHS, the Chemical Toolkit and other workplace tools.
    - Include GHS phrases in the IPCS International Chemical Safety Cards (WHO-PCS, ILO).
3. Build and promote the Occupational Risk Management Toolbox, through the following:
    - Development of toolkits for workplace hazards other than chemicals (lead group ILO, WHO, IOHA, NIOSH, linking to an expanded network of other international and national bodies).
    - Integration of other toolkits in WHO CC Workplan (WHO CC [Collaborating Centers] Task Force on Preventive Technology).
    - Adaptation of existing participatory processes that have effectively engaged local communities (e.g., WISE, WIND programme) (ILO).
4. Explore new partnerships for implementation, including the following:
    - International bodies involved in implementation of the GHS, for example to tap into GHS implementation and training workshops (ILO).
    - The International Association of Labour Inspectors (IALI) (ILO to lead).
    - Identify potential donors and granting bodies.
    - Use country to country partnerships (twinning), for example between a developed and developing country.
5. Foster the development of workplans in support of this Strategy, focusing on specific applications, industry/occupation situations, countries or regions and maintain links with national and other working groups established to implement workplans. Workplans will aim

to influence local decision-makers and effect local implementation. Information about workplans will be included in the Clearing House (see below).

6. Identify ways to influence national decision-makers, including through:
   - WHO CC network activities
   - ILO-CIS Network.
   - ILO and WHO offices.
   - The EU.
   - Agenda of inter-governmental meetings, e.g. on EU-US Cooperation.
   - Promotion at international and national Occupational Safety and Health/Industrial Hygiene Conferences.
   - Holding annual or bi-annual international CB workshops (1st workshop held November 2002; 2nd workshop held March 2004). The 3rd workshop was held in September 2005 at the IOHA 6th International Scientific Conference (South Africa) and concurrently the XVII World Congress on Safety and Health (Orlando, FL). IOHA meeting was conducted back-to-back with WHO CC meeting.
   - WHO CC Network meeting (Milan, June 2006) back-to-back with ICOH meeting provides an option for CB planning meeting and training.
7. Develop and publish a research agenda (lead: University of Oklahoma, working with other leading agencies, for the ITG), including sector-specific research (construction, agriculture, mining). This would include the areas listed below and would be updated regularly based on technical progress. A current research agenda will be maintained on the Web site (refer below), and at Annex 2. Research agenda will need to include application of the CB technique to different hazards, e.g., chemical, biological, physical, ergonomic exposures,

etc.; different industry situations, e.g., SMEs, large industries, multi-nationals; developing countries; and developed countries.

8. Collect and communicate research and information, including the following:
   - Maintenance of the Web site, hosted by ILO, with links to other relevant websites (lead: ILO).
   - Augment the Web site with a Clearing House including a web-based directory of research and validation studies (researchers list their ongoing studies and references for completed work).
   - Include other activities in the Clearing House, such as workplans developed by countries, etc.
   - Include a repository of guidance sheets in the Clearing House. Centers could be identified (regional, language-based) to maintain these (e.g., NIOSH), linked to the ILO Web site.
   - Publish regular update/topical articles in newsletters by email/net. Use existing vehicles and meetings to distribute (IOHA, NIOSH, Global Occupational Health Network Newsletter, etc).
9. Develop and maintain a capacity building and training plan, focusing on developing countries (WHO-OEH). This will be needed for piloting work, then during the full-scale implementation. It would include the following:
   - Explore use of the GTZ Chemical Management Guide to build capacities and prepare countries for implementation of the Chemical Toolkit.
   - Cultivate regional train-the-trainer core groups.
   - Conduct train-the-trainer workshops in conjunction with other international/regional events.
   - Provide generic training materials that can be translated for local use.

10. Maintain an ITG to oversee the Global Implementation Strategy (quarterly telephone conferences, with face-to-face meetings occurring back-to-back with other events where possible) (WHO-PCS).

Further Information

Further information can be obtained from the following Web site:

http://www.ilo.org/public/english/protection/safework/

IPCS International Technical Group (ITG)

Terms of Reference and Membership

Terms of Reference

1. The functions of the ITG are:

    1.1 To facilitate the further development and implementation of an Occupational Risk Management Toolbox, in particular the International Chemical Control Toolkit.

    1.2 To maintain a Global Implementation Strategy, including identifying lead bodies for key actions.

    1.3 To provide guidance to the relevant lead body/bodies concerning the collection and dissemination of information on activities.

    1.4 To coordinate other activities undertaken in support of the Global Implementation Strategy, in particular, those of its members.

    1.5 To measure and communicate progress against the Strategy.

2. The ITG makes its recommendations and decisions by consensus of those members present at a meeting.
3. The roles of Chair and Rapporteur alternate between the IPCS partners, i.e. ILO and WHO.
4. The ITG normally meets quarterly by teleconference. The ITG may agree to hold face-to-face meetings from time to time, and in this circumstance, participants make their own arrangements for bearing the cost of attendance.

Membership

The members of the ITG are experts from the following organizations:

American Industrial Hygiene Association (AIHA)

GTZ Convention Project on Chemical Safety, Germany

International Labour Organization (ILO)

International Occupational Hygiene Association (IOHA)

Health and Safety Executive (HSE), Great Britain

National Institute for Occupational Safety and Health (NIOSH), United States

World Health Organization (Occupational and Environmental Health (OEH) and Programme for the Promotion of Chemical Safety (PCS))

International Research Agenda

An international research agenda will be developed and published (see Strategy Element 7). Proposals that have come forward to date are listed below.

1. Chemical Toolkit Applications in Developing Countries
    - Investigate applications within large enterprises.
    - Develop tools for SMEs.
    - Effectiveness of predicting exposures.
    - Validation of controlling exposures.
    - Field test of current product.
    - Translation of concepts and common phrases.
2. Other Applications in Developing Countries
    - Focus on large scale industries, select appropriate industries and hazards.
    - Develop other toolkits for the Occupational Risk Management Toolbox.
    - Adapt existing approaches (WIND Program), build on successes.

- Develop an ergonomics toolkit based on existing models.

3. Chemical Control Toolkit Applications in Developed Countries
   - Further validation studies.
   - Validate controlling exposures in selected small business trades.
   - Field industrial hygiene input on expanding, ranking hazards, prioritizing controls.
   - Focus on small business trades and define success.
4. Other Applications in Developed Countries
   - Develop Ergonomics Toolkit based on existing national models.
   - Expand industrial hygiene aspects to include physical and biological exposures.
   - Investigate Occupational Risk Management Toolbox concept for SMEs.
5. Research to Fill Gaps in the Chemical Toolkit
   - Investigate applications to the skin route of exposure.
   - Integration of skin and inhalation routes of exposure.
   - Integration of useful elements from comparable tools, e.g. the German Column Model.