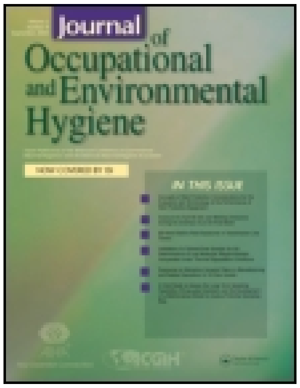

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History and Evolution of Control Banding: A Review

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Control banding (CB) strategies offer simplified solutions for controlling worker exposures to constituents often encountered in the workplace. The original CB model was developed within the pharmaceutical industry; however, the modern movement involves models developed for non-experts to input hazard and exposure potential information for bulk chemical processes, receiving control advice as a result. The CB approach utilizes these models for the dissemination of qualitative and semiquantitative risk assessment tools being developed to complement the traditional industrial hygiene model of air sampling and analysis. It is being applied and tested in small- and medium-sized enterprises within developed countries and industrially developing countries; however, large enterprises have also incorporated these strategies within chemical safety programs. Existing research of the components of the most available CB model, the Control of Substances Hazardous to Health Essentials, has shown that exposure bands do not always provide adequate margins of safety, that there is a high rate of under-control errors, that it works better with dusts than with vapors, that there is an inherent inaccuracy in estimating variability, and that when taken together the outcomes of this model may lead to potentially inappropriate workplace confidence in chemical exposure reduction in some operations. Alternatively, large-scale comparisons of industry exposure data to this CB model's outcomes have indicated more promising results with a high correlation seen internationally. With the accuracy of the toxicological ratings and hazard band classification currently in question, their proper re-evaluation will be of great benefit to the reliability of existing and future CB models. The need for a more complete analysis of CB model components and, most importantly, a more comprehensive prospective research process remains. This analysis will be important in understanding implications of the model's overall effectiveness. Since the CB approach is now being used worldwide with an even broader implementation in progress, further research toward understanding its strengths and weaknesses will assist in its further refinement and confidence in its ongoing utility.

Keywords chemical hazards, control banding, risk assessment, risk management, toolbox

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INTRODUCTION

A foundation of the modern movement for control banding (CB) strategies is derived from programs initiated in the United Kingdom (UK) by the Health and Safety Executive (HSE). The need to provide guidance and assistance to small- and medium-sized enterprises (SMEs, which employ about 90% of the UK work force)[(1)] in meeting requirements to conduct risk assessments of chemical exposures led to the HSE development of a program known as the Control of Substances Hazardous to Health (COSHH) Essentials.

In 1998, the HSE published a series of papers outlining a CB strategy of creating a model in which the hazard was combined with the potential exposure to determine a recommended level of control approach. European Union (EU) risk phrases were used to rank the hazard of a chemical, and potential for exposure was estimated by the quantity in use and the volatility of liquids or dustiness of solids. The scheme uses information associated with hazardous chemicals to develop hazard groups. These hazard groups are derived for a variety of chemicals and are designated by experienced toxicologists. When a hazard group associated with a chemical is selected by the manager of an SME, toxicological expertise is utilized without the need for an on-site expert. This is an important foundation for the eventual consideration of the exposure potential to the chemical.

The remainder of the decision-making process includes the volume of chemical used and likelihood of the chemical becoming airborne, estimated by the dustiness or volatility of the source compound. When these parameters are entered into a work sheet, the suggested control approach is identified. The end product is the selection of a control guidance sheet with both general and specific advice for common tasks.[(2)]

In the development of the CB model, Maidment[(3)] stressed the importance of limiting the number of factors in the model to reduce its complexity and increase its applicability for non-experts. Although in theory there can be a stratification of risk across many levels, each additional level leads to a more intricate tool for the SME manager, which as an end

ACRONYMS

ABPI	Association of the British Pharmaceutical Industry
BAuA	Federal Institute of Occupational Safety and Health (Germany)
BOHS	British Occupational Hygiene Society
CB	Control Banding
CEFIC	European Chemical Industry Council
CEMAS	CEFIC Exposure Management System
CGS	Control Guidance Sheets
CIA	Chemical Industries Association
CHIP	Chemical Hazardous Information and Packaging
COSHH	Control of Substances Hazardous to Health
EASE	Estimation and Assessment of Substances Exposure
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemical Agency
ECP	Exposure Control Practices
EINECS	European Inventory of Existing Substances
EU	European Union
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
GTZ	Society for Technical Cooperation (Germany)
HHE	Health Hazard Evaluation
HSE	Health and Safety Executive (UK)
HSDB	Hazardous Substances Data Base
ICCT	International Chemical Control Toolkit (new name of the ILO Toolkit)
IH	Industrial Hygiene
ILO	International Labor Organization
IOHA	International Occupational Hygiene Association
LE	Large Enterprises
LEV	Local Exhaust Ventilation
LOAEL	Lowest Observed Adverse Effect Level
MAK	Maximum Allowable Concentrations (Germany)
MoE	Margins of Exposure
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NOAEL	No Observed Adverse Effect Level
OEB	Occupational Exposure Band
OEL	Occupational Exposure Limit
ORM	Occupational Risk Management
PACE	Prevention and Control Exchange
PB-ECL	Performance-Based Exposure Control Limits
PPE	Personal Protective Equipment
PPM	Parts per million
REACH	Registration, Evaluation, Authorization, and restriction of Chemicals
RTECS	Registry of Toxic Effects of Chemical Substances
SME	Small- and Medium-Sized Enterprises
SQRA	Semiquantitative Risk Assessment
TLV	Threshold Limit Value
TWA	Time-Weighted Average
UK	United Kingdom
US	United States
WHO	World Health Organization

product may hamper its overall intended utility. To achieve this balance of simplicity and effectiveness, Maidment suggested four categories, or "bands," to assist in preventing exposure to chemicals. These four control strategies are a grouping of three levels of engineering containment based on sound industrial hygiene (IH) principles, with professional IH expertise as a fourth category. Within this model, these generic control strategies also have been adapted to address chemical exposure potential where the control guidance sheet (CGS) approaches may not be appropriate or practical. These other CB strategies utilize the banding approach to assist in directly assigning personal protection equipment (PPE), such as an appropriate level of respiratory protection and addressing dermal exposure potential.(1)

In a historical context, the banding of risk began in the 1970s and 1980s relating to explosive events, radiation, lasers, and biological agents. The pharmaceutical industry should be credited with the initiation of exposure control categorization utilizing an industrial hygiene basis(4,5) with its work in the late 1980s and early 1990s. During this period, approaches to protect workers handling products with limited pharmacological and toxicological data led to efforts to stratify toxicological hazards and link them directly to simplified, commensurate control strategies during the production phases of product development.(6,7)

These control approaches for pharmacological agent exposures were divided into five hazard categories.(5) This effort to address the growing potency of newly developed compounds followed the path of the microbiological and biomedical industries controlling exposures to increasingly toxic microorganisms within the four categories of the Biosafety Level approach.(8) Formally, the establishment of in-house occupational exposure bands (OEBs) by the Association of the British Pharmaceutical Industry (ABPI)(9) assisted the product development phase of the industry to achieve a method for compliance with the COSHH regulations in a manner later adapted to the COSHH Essentials to address chemical exposures.

There were several forces beyond the regulatory realm that also led to the CB model's adaptation and expansion into the chemical arena. Perhaps the most significant was the recognition that the traditional process of establishing occupational exposure limits (OELs), against which measurements of airborne concentrations of chemicals could be compared to ensure that exposures are controlled, was quickly losing ground by orders of magnitude to the increasing number of chemicals posing a threat to worker health.(1) Forces that drive the evolution of the CB model continue to this day. The nanotechnology industry is seeing itself akin to pharmaceutical and microbiological industries in that they are facing similar limitations in toxicological data. A CB model that addresses exposure to nanoparticulate recently has been presented in concept as a practical approach to achieve exposure control in the absence of this data.(10)

REVIEW OF CB LITERATURE

The peer reviewed literature on CB approaches (mostly relative to COSHH Essentials) can be summarized according to the development of the models, the use of databases to support the models, and the models' validation. CB has its roots in a number of qualitative(11) and semiquantitative(12) risk assessment approaches that began to appear in the 1970s and evolving in the 1980s relating the assessment of catastrophic failure probabilities at large chemical facilities.(13) An example of this is a risk matrix describing the likelihood and probable severity of an event, e.g., an explosion or release of toxic material developed for use by a large chemical enterprise. As Money(13) presented, there are a number of relevant strategies that were borrowed from and built on during previous efforts, and it is not always possible to trace the steps by relying on chronological appearance in the peer reviewed literature. What is evident is that there was much exchange of information and ideas among occupational health practitioners and scientists in the chemical, biological, and pharmaceutical industries during that period.(1,5,14)

Model Development

Linking Toxicology to Control

In an early, perhaps the first, published report in which toxicological data were linked directly to an appropriate level of control. Money(14) presented a structured approach to design and operation of a chemical plant that handles aromatic amines, nitro compounds, and equivalent agents with carcinogenic potential based on a carcinogenic ranking system. 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. It was truly simple in that it utilized a basic exposure scenario where the only determinant of exposure was the veracity of the toxicological data. Money suggested that this approach, which covered both inhalation and skin contact, should be applicable to similar approaches ranking relative hazards of chemicals.(15−17)

This toxicology-to-control approach described by Money(14) began by using four categories of toxicological outcome relating to carcinogenic potential, collapsed from a system utilizing six(18) that considers 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. Linearly matched with these four levels of carcinogenic potency were four levels of controls, progressing in complexity and stringency. Putting them together, these toxicology-to-control levels are then summarized as: (1) for all chemicals, use good basic IH; (2) for suspected animal carcinogens, increase to isolation of moderate exposure potential; (3) for suspected human carcinogens with moderate exposure potential, increase to containment and regular audits; and (4) for proven carcinogens with low exposure potential, increase to automated bulk transfers and process control.

The toxicology-to-control model was also applied by Nauman et al. in 1996(5) to exposures to pharmaceutical active ingredients in laboratory and manufacturing operations. The pharmaceutical industry traditionally had used risk assessment methods to establish OELs for active ingredients; however, the increasing potency of these agents led to a new approach based on the Biosafety Level concepts used in laboratories. Substantiated by a large database of air monitoring data for various operations, they were able to distinguish five hazard categories (or performance-based exposure control limits, PB-ECL), based on toxicological and pharmacological properties of these agents and on the engineering controls and administrative procedures known to be effective in controlling exposure levels.

The Chemical Industries Association (CIA) further addressed toxicological information for chemical agents in their guidelines for safe handling of colorants (second version).(19) In this document, inputs of hazard categorization (1–4), hazard classification (e.g., toxic, corrosive), associated risk phrase, and guideline control level (8-hour time-weighted average [TWA]) were linked to control recommendations for each hazard category. As both the CIA guidelines and the COSHH regulations were created in the U.K., an ongoing discussion of chemical agent models began to develop. According to Guest(20) 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 Substances (EINECS).(21) These factors led the CIA to develop chemical categorization guidelines for their member organizations.

Building on the earlier CIA guidance (1993)(19) and the work of Gardner and Oldershaw (1991),(16) the later CIA guidelines (1997)(22) incorporated the Chemical Hazardous Information and Packaging (CHIP) Risk Phrases and guideline control levels, in addition to data on adverse effects in humans. 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 be developed only 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 is usually limited to approximately four levels, this approach was designed to cover six orders of magnitude, plus a special category. 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 in the COSHH regulations (10 mg/m^3).

The Exposure Prediction Step

At this juncture, no one had yet factored the *probability of exposure* into the risk assessment and risk management aspects of a CB model. 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's[23] review on the methods of studying the determinants of exposure included work tasks, equipment used, environmental conditions, and existing controls. In evaluating the risk, a dedicated exposure model was used that is based on Cherrie and Schneider[24] by providing subjective exposure assessment using a structured approach based on descriptive workplace activities and environment. Using this model, subjective exposure assessment showed significant correlation with exposure measurements across 63 jobs and four different agents (asbestos, toluene, mixed respirable dust, and man-made mineral fibers). This serves as an excellent example of how dissecting existing models can lead to criteria to be used in developing other exposure control models and future toolkits.

In studies of determinants of exposure reviewed by Burstyn and Teschke,[23] there was little attention devoted to volume of product used, and less to the physical characteristics of chemicals in use. The HSE played a pivotal role in developing a regulatory approach based on these concepts used to date.[25,26] While the work of the HSE was based in large part on that of the UK CIA,[20,22] which categorized substances into OEBs, it is apparent from the preceding discussion that many other groups have contributed to the development of COSHH Essentials. The challenge facing the HSE was to develop guidance that was practical for SMEs, used available hazard information, was easy to use and understand, and which relied on readily available information (Table I). These goals can be realized by using European risk phrases (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.

The COSHH Essentials approach, as it later came to be known, builds on earlier approaches.[5,14,16,22,27,28] It also offers two other significant advances: it is specifically developed for SMEs and it includes control advice. The key components of the model include the hazard banding, exposure potential, and control approaches. Hazard banding is described more fully below.[26] It is important to point out, however, that from a British perspective, COSHH Essentials is limited to substances classified under CHIP, thereby excluding, e.g., pesticides and pharmaceuticals, which are outside the scope of those regulations, and also process-generated hazards such as wood dust, silica dust, and welding fumes. Exposure banding is a function of physical properties leading to likeliness for the material to become airborne (volatility of liquids or dustiness of solids, and the quantity in use).[3] These elements are combined to determine the appropriate control approach (Table II). Therefore, there is perhaps a stronger link in the modern evolution of the CB model to the work of Burstyn[23] and Cherrie[24] than to the earlier toxicology-to-control approaches. Later versions of COSHH include PPE Essentials, offering advice for gloves and respirators, and for addressing dermal risks. Another feature of the COSHH Essentials website 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).

The developers felt that operation-based control guidance sheets (CGS) would provide the best format for advising SMEs. The approximately 300 CGS[29] now available are structured according to a standard format. This format contains sections on 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 an employee checklist for proper utilization of controls. Russell et al.[25] states that use of the scheme will not in itself constitute a suitable and sufficient workplace risk assessment; it must therefore be considered as guidance and not a replacement for traditional IH. 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 and suitability of controls. Similarly, it was pointed out that an overprotective approach would lack credibility and deter promotion efforts and implementation, whereas an underprotective approach would not protect workers. Weighing these factors, it was generally agreed in the model development that a conservative approach would be the most responsible.

Brooke[26] outlined three criteria for the toxicological basis of the UK approach: (1) simple and transparent, (2) make best use of available hazard information, and (3) recommend control strategies that vary according to degree of health hazard. The R-phrases that are agreed to throughout the EU facilitated these criteria, as they address all relevant toxicological end points. This idea had been proposed previously by Gardner and Oldershaw[16] and had formed the basis of similar strategies.[9,22,27] Brooke noted differences between

TABLE I. Factors Used in HSE's Core Model

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

Note: Source is Ref. 25.

TABLE II. Control Approaches Used in COSHH Essentials

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

Note: Source is Ref. 25.

these approaches and that of the HSE. COSHH Essentials include alignment between dust and vapor target exposure ranges and dose level cutoff values and 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."[9,20,22]

Brooke's[26] article achieved two goals: first, it explained the assignment of R-phrases to the Hazard Bands A–E utilized in the COSHH Essentials; and, second, it compared these assignments with health-based OELs. The hazard bands, which are based on toxicological considerations, are each divided by an order of magnitude in concentration range. As the relationship between the 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 that oversaw development of this approach decided to adopt a pragmatic approach and to align the exposure bands as seen in Table III below. 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."

In writing about the development of the model, Maidment[3] stressed the importance of limiting the number of factors in the model to control its complexity and applicability. This simplicity was to be balanced with the hazard and exposure potential parameters necessary to predict an adequate control strategy. Toward this end, control strategies were collapsed into four main categories (Table II). Since characteristics of exposure potential can be summarized as those related to physical properties and those related to substance handling, Maidment focused on the dustiness of solids and the volatility of liquids. The study indicated 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 vs. operating temperature, separated into three regions: low, medium, and high volatility. As a subsequent characteristic of operational factors, the scale of the operation was classified as small-scale, medium-scale, and large-scale.

With these three articles[3,25,26] 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. It meets all six of Money's[13] core principles (understandability; availability; practicality; user friendliness; confidence on the part of users; and transparent, consistent output). While welcoming the move by HSE to provide guidance in the form of CGS, Hudspith and Hay[30] pointed out an additional obstacle to worker protection: communications barriers within companies. They recommended that HSE continue to stress the value of work force involvement in health and safety issues. Despite its attributes, however, the COSHH Essentials model is subject to a number of limitations

TABLE III. Allocating R-Phrases to Hazard Bands

Hazard Band	Target Airborne Concentration Range	R-Phrases
A	>1–10 mg/m^3 dust; >50–500 ppm vapor	R36, R38, all dusts and vapors not allocated to another band
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	Seek 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: Source is Ref 26.

relative to the development of the model, development of databases, use of the model, and its validation and verification.

Validation and Verification

For purposes of this article, validation focuses on the establishment of the soundness of a given model, whereas verification requires the evidence necessary to confirm its effectiveness. While it would be useful to validate a variety of the CB strategies proposed, only COSHH Essentials has been developed and implemented to the point that it has been the subject of almost all validation efforts. Also receiving attention is the International Labor Organization (ILO) Chemical Control Toolkit (ILO Toolkit), produced in collaboration with the HSE and the International Occupational Hygiene Association (IOHA). The ILO Toolkit is based on the HSE COSHH Essentials and is adapted for use worldwide.[31] For validation purposes, three aspects of model evaluation were applied by Tischer[32] to COSHH Essentials. These aspects to validate the model include: internal (conceptual) validation of the model's assumptions and structure, external (performance) validation of the model predictions corresponding to professional IH monitoring data, and operational analysis of the understanding and implementation of the model's outcomes respective to its target group.

However, before presenting these model aspects, there are still many questions to be answered in all three categories. Kromhout[33] 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 an 8-hour shift to be between threefold and 4000-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[34] responded that these arguments ignored the range of competencies in the workplace, and the number of firms handling chemicals; however, he concurred that the use of "quality exposure data is extremely valuable for assessing the effectiveness of control measures." Topping did not directly address Kromhout's variability concern; he relied on the premise that the COSHH Essentials model is not intended to replace monitoring, but rather, it provides needed help to SMEs. Topping pointed 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 the British Occupational Hygiene Society (BOHS) experts, and that there had been no complaints about the recommended controls being too stringent without addressing the lack of research to show that the controls have even been put into place, let alone that they have been verified to achieve the intended exposure control. Kromhout[35] replied that he and the editor of the *Annals of Occupational Hygiene* questioned the role of tools like COSHH Essentials in the "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 evaluated properly prior to release, and that peer review by BOHS experts could not replace the rigorous evaluation of testing for reproducibility, validity, and peer review of results in the scientific literature. It was recommended that COSHH and EASE be used in the initial screening process.

According to Maidment,[3] the core model was validated by predicted dust and vapor exposure ranges, and their corresponding three-tiered hierarchy of engineering controls 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 during the model's development and validation and specifically involved the HSE Advisory Committee on Toxic Substances (including Guest, Brooke, and Money) and experts of the BOHS.[3,36] When taken as a whole, Topping did not address Kromhout's concerns of this unpublished peer review process. Therefore, not addressed are the potential weaknesses that one might find in the scientific literature when internal and external validation of the model is performed.

Brooke's[26] work in comparing the R-phrases and resulting target airborne concentrations to the relevant health-based OELs on national lists (UK and German Maximum Allowable Concentrations, MAK) began to address the first category on internal validation for the COSHH Essentials. The work of Jones and Nicas[31] reported below looked at both internal validation of the ILO Toolkit as compared with the UK HSE model and the external validation of the COSHH Essentials. The work of Tischer et al.[32] and Maidment[3] focused on the external validation and began to answer some of the questions relating to performance validation. A glaring weakness in the research at this time is present regarding the operational analysis of the given CB models.

Brooke was the first to identify the inherent difficulty in assigning dusts and vapors to equivalent bands designated elegantly by orders of magnitude (Table III). Resulting from this alignment of the bands, dusts have a higher margin of safety than vapors, especially for repeated exposure toxicity based R-phrases. Emphasizing the generic nature of this CB model and its provision for "adequate control," Brooke concluded that the margins offer "considerable reassurance" for vapors and "even greater reassurance" when used for dusts. Much of the model's weakness in this regard was balanced against the intended non-expert SME end user with no risk assessment background. With this in mind Brooke explicitly noted that the model used in practice would require "continued evaluation of the allocation of the R-phrases to the hazard bands, such that the scheme may be revised and improved in the light of practical experience."[26] Brooke also 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.

It must be pointed out that the Hazard Band values are generally in the same order of magnitude as OELs (see Table III) and also that it is not uncommon for acceptable risk levels of OELs, which are based on a 40-hour work week that accounts for worker recovery periods, to be in the range of 10^{-4} to 10^{-3}. In contrast, acceptable risk values in environmental settings, which are based on continuous, involuntary exposure (168 hours per week) of all members of the population with no recovery period,[37] are in the range of 10^{-6} to 10^{-5}. Without understanding the basis of these underlying risk parameters, the problem then lies more in the lack of overall acceptance of higher-risk levels for occupational settings as compared with environmental settings. Solving this issue will require an improved communication of the reasons behind this risk differential and, therefore, a greater understanding of risk acceptability in occupational settings.

Jones and Nicas[31,38] reported less positive results in their evaluation of the ILO Toolkit. 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 revisions. They concluded that the 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 1000 to 10,000 for R48/20 *(Danger of serious damage to health by prolonged (inhalation) exposure)*, depending on whether the NOAEL or LOAEL was utilized as the basis of calculation. That study made these calculations based on the generic COSHH criteria, to avoid any errors caused by incorrect assignments of hazard bands.

A comparison of the R-phrases (taken from the 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 seen 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[31,38] suggested that the authors of the ILO Toolkit should reconsider the hazard classification plan, as the variations among CB strategies reduce trust on the part of users. Based on the small safety margins between doses that cause significant effect in animals and the exposure bands in the toolkits being evaluated, they also suggested target exposure levels be made available to end users. Without offering these to the user to evaluate whether exposures are in line with the minimal margin, a false sense of health protection in the workplace is permitted.[38]

Tischer[32,39] and colleagues at the Federal Institute of Occupational Safety and Health (BAuA) conducted the first and most complete external validation of the COSHH Essentials to date, based on independent measurement data. The primary empirical basis for their analysis was measurement data collected within the preceding decade during several BAuA field studies. Some data were also provided by the chemical industry. Tischer's team also set out to address the external validation of the COSHH Essentials exposure model. While stating that the accuracy of the model was represented by agreement between predicted and observed, they believed that statistical tests are not useful due to the uncertainties in empirical data such as variability, errors in measurements, or false or incomplete information. Due to a lack of available data for some professions, only those with more complete data sets were used in this study. There were apparently 958 data points available for evaluation: 732 for liquids, and 226 for solids.

The BAuA data were all obtained from their own laboratories, and all workplace measurements were conducted as per the German Technical Rules. Sampling durations were usually 1-4 hours, and were task based, i.e., they corresponded to a specific scenario. Over 95% were personal samples. Sources of uncertainty considered were volatility / dustiness, scale of use, and control strategy.

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 requiring 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.) Because of the limited quantity of data available, these researchers limited their analyses to scenarios in which the control strategy could be determined from the historical reports, generally matching one of the four control strategies. Comparisons of the predicted and actual data were conducted using frequency polygons overlaid with the range of predicted values and by calculating the percentage of the cases that were correctly or incorrectly predicted. Most of the data points fell within the predicted ranges.

Per Balsat et al.[12] Tischer[40] found that the 95th percentile of data from different operations fit within the ranges predicted by the COSHH Essentials model. Exceptions were scenarios where some of the limited data points for solvent exposures were above the predicted range, such as in carpentry workshops and with adhesives applications where the chemical products are spread over a large surface area reflecting small-scale, dispersive operations. Exceedances also occurred in the handling of powdery substances in kilogram quantities under local exhaust ventilation.

Jones and Nicas[41] also performed external validation by evaluating the ability of the COSHH Essentials to select an appropriate control approach and whether these controls achieved reduction of exposure concentrations. They compared reported air monitoring data and related use of ventilation systems, taken from the National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations (HHEs) for 34 vapor degreasing operations with 7 different solvents and 22 bag filling operations with 19 particulates. R-phrases for these liquids and dusts were obtained from the HSE National Chemical Emergency website (8 substances), the Australian Approved Criteria for Classifying Hazardous Substances (2002) and the Hazardous Substances Data Base (HSDB) of the United States (US) 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 the NIOSH HHEs. Using this information, Jones and Nicas 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 control technologies, such as local exhaust ventilation (LEV) (under-control errors), and situations in which sufficient exposure control occurred in the absence of control technologies (over-control errors). They found under-control error proportions of 78% of the 179 cases where LEV was present in vapor degreasing operations, and in 48% of the 159 cases where control technologies were present in bag filling operations.[41]

Their findings led Jones and Nicas[31,41] to multiple conclusions. They found that the exposure bands do not provide consistent, or adequate, margins of safety and the high rate of under-control errors highlighted the need to evaluate the effectiveness of installed LEV systems using capture efficiency and/or air monitoring techniques. The limited assignment of "dustiness" ratings to dusts complicates the model's process and indicates that specific guidance must be provided in cases where there is insufficient or inappropriate hazard information, and that guidance on contacting professional assistance for engineering controls should be included on Task Guidance Sheets. Additionally, the R-phrase procedures, which include concentration "cutoff" values (e.g., the hazard classification would not be for a mixture with <x% of the substance), are not compatible with U.S. regulatory practice, which may result in measurements of the airborne concentrations of the constituents of a mixture, regardless of their percentage composition in the mixture.

Ruden and Hansson[42] investigated the accuracy of the EU classifications for acute oral toxicity for 992 substances by comparing their acute toxicity categorization ("very toxic," "toxic," and "harmful") to the acute oral toxicity data available in the Registry of Toxic Effects of Chemical Substances (RTECS). Acute oral toxicity in rats is used because, although of minor importance for the complete toxicological profile, it offers a gauge of immediate toxicity with many substances lacking long-term data. They found that of the 992 substances that had enough data to undergo this evaluation,15% (152) were assigned too low a danger class, and 8% (79) too high. Of those too low, or underclassified, 26 should be classified as "very toxic," 49 should be "toxic," and 77 should be "harmful."

According to Ruden and Hansson, the EU classifications rules indicate that once a substance is placed into a category based on specific toxicological data, it cannot be downgraded to a lower category based on additional information. It is when different studies of appropriate scientific quality would lead to different categorizations that the rules are less clear. In this instance, the authors indicate that there is an "informal policy" in the EU to base its final classification on the most adverse outcome. A number of possibilities for this underclassification issue were noted, including variations in toxicity data from different laboratories; however, more issues arise relating to the EU informal policy. If the EU Commission has access to data not in RTECS, and these data support higher classifications, then the policy should default a substance categorization to a higher hazard class and not a lower one. Other possibilities exist such as the frequency of updating classifications, insufficient toxicity data searches, or problems with the RTECS database. Regardless, it is difficult to accurately pinpoint a causal relationship, as there is a "lack of transparency" in the Commission's classifications. For future classifications of substances the authors recommended the scientific basis be published to afford this transparency, so when similar issues arise they can be addressed and rectified.[42]

Although not always recognized as a validation parameter, the COSHH Essentials' CB model had ease-of-use and simplicity as intended design parameters for the non-expert end user.[3,26] Therefore, the results of an HSE survey to determine the utility of the COSHH Essentials should also be considered. A telephone survey was performed with 500 chemical purchasers who have used the older, paper version of COSHH Essentials.[43] The survey indicated that it had been utilized by 80%, with only 5% finding it difficult to use and 95% willing to recommend it to other companies. In addition, 75% of those surveyed had taken action to control chemical exposures. Actions taken when utilizing the COSHH Essentials model included: chemical substitution (18%), changing work procedures (25%), changing the control measure used (36%), providing information or training to workers (48%), and checking existing control measures to ensure they are working (67%).

Variations of the Chemical Model

Users of CB strategies quickly realized that one strategy would not fit all needs. Variations of the model and its use in practice have been developed by several nations, including France, Germany, Belgium, Norway, The Netherlands, Singapore, and by corporations, and are in development in India, Korea, and Japan. Interest in CB strategies on the part of the European occupational hygiene community was spurred by the introduction of the Chemical Agents Directive in 1998.[13,44] Several approaches have resulted. The French approach[45] 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. In June 2007, a new European law on chemicals, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), entered into force; at the same time, the European Chemicals Agency (ECHA) began operations. This law shifts greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances.[46] The European

Chemical Industry Council (CEFIC) exposure management system (CEMAS)[13,47] intends to provide a guidance tool for SME, 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.

The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)[48] approach is a tiered and targeted risk assessment that could aid in the registration of large numbers of chemicals under REACH. This is a streamlined approach that applies CB concepts in a tiered manner with Tier 0 screening out chemicals not presenting an immediate risk to humans or the environment; Tier 1 identifying 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. Toward that end, a database known as Solbase shows potential as a source from which CGSs could be developed. With partners from throughout Europe, Swuste et al.[11] have tested Solbase both for usability of the software and suitability of the recommendations yielded by Solbase, using 535 new and existing solutions. Although most of these solutions currently relate to manual or material handling, noise and vibration, machine guarding, and other safety issues, few address air contaminants. The databank can be queried either by production process, or by hazard.

Much of the literature for the evaluation and validation of CB models has been related to a concerted effort to create and drive a research agenda through workshops. This approach has been proven useful for developing earlier solutions-based programs beyond their national origin. Early solution-based initiatives include the noise control solutions from the UK HSE,[49] exposure reduction in mining from Australia,[50] and chemical substitution strategies from Denmark, the UK, the United States, and The Netherlands to reduce health hazards.[51] A model for communication and evaluation of these programs began at the first IOHA Scientific Conference in 1992 with a workshop on sharing knowledge of preventive measures. This culminated in World Health Organization (WHO) experts meeting in 1994 to stimulate the interchange of solutions toward the reduction of occupational risk and the formation of the Prevention and Control Exchange (PACE) working group.[52] This process has evolved into efforts such as the European Solbase, with many nations teaming together to develop a database of effective controls for workplace hazards and reduction of occupational risks.[11]

International CB workshops have been held in London (2002), Cincinnati, Ohio (2004), and South Africa (2005). The workshops have led to an international agreement for coordinating the work of international agencies and their partners and a global implementation strategy for CB models. An example of this collaboration is the appropriate international forum that the workshops have provided for the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS is a uniform, internationally developed, and standardized protocol for the toxicological basis for assigning chemicals to standardized hazard statements on labels and safety data sheets in manner that builds on the EU R-phrase process.

From the beginning of the UK model's development it was made clear that when more data became available, chemical substances would need to be reclassified.[20] Should there be future reclassification efforts, it has been recommended that the scientific basis and decision matrix for these hazard classifications be standardized and readily available to achieve transparency for subsequent evaluations.[42] GHS is presented as a proper approach to build transparency to the process by including a core set of label elements to work toward harmonized hazard statements for each category and class of chemicals covered. It also has a harmonized approach to classifying mixtures of these chemicals. The International Program on Chemical Safety has also adopted the concept of the ILO Toolkit as part of its overall process to include exposure control approaches in parallel with its efforts for a chemical standardization process. While this may take some time to accomplish, it will eventually provide consistency of information on more than 1500 commonly used chemicals and include a centralized procedure for frequent updates of information.[53]

Through these CB workshops, a process emphasizing the utility of available CB models has also led many countries to adapt and use them within their existing occupational risk management approaches. A two-stage risk assessment strategy (Regetox) was developed and tested in Belgium[12,54,55] in response to the European Chemical Agents Directive 98/24/EC,[44] which requires companies to assess and manage chemical risks in the workplace. To minimize the number of chemicals (and resulting costs) for which risk assessment must be conducted, the first stage of the strategy utilizes the French "ranking of potential risk" based on R-phrase, annual quantity in use, and frequency of use, as described above.[56] Only products receiving a rating of medium or high are carried forward to the second stage, which utilizes the COSHH Essentials. When mixtures are being handled, the risks are evaluated for each harmful component according to the composition by weight of the mixture.[12]

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 MSDS. 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.[56]

The Semi-Quantitative Risk Assessment (SQRA) developed in Singapore is intended to facilitate identification of chemical hazards, evaluation and potential for exposure, risk level determination, and prioritization of appropriate controls to address the identified risks. With the SQRA there are three methods for performing exposure evaluation that include (1) personal exposure monitoring, (2) using exposure factors and parameters, (3) and/or applying empirical and theoretical formulas to estimate exposures at the plant or process design stage. The ILO Toolkit, which was renamed as the International Chemical Control Toolkit (ICCT) during the SQRA's development, was tested in parallel with applications of the SQRA to evaluate their utility and to perform comparisons based on theoretical and empirical aspects.[57]

Direct comparison of the two approaches was stratified by their respective control approaches as compared with the SQRA risk level approach. 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 metalworking, 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 any differences between the control approach and risk level being, at most, one to two bands. In the majority of cases using the empirical comparison it was determined that the Toolkit overevaluates the risk relative to SQRA, leading to more conservative approaches relating to controls.[57]

Germany is the third largest chemical producer in the world and the largest chemical exporter in the world.[58] As such, it has taken its responsibility to assist in sound management of chemicals in developing countries.[59] Under its Convention Project on Chemical Safety, the technical arm of the German Development Agency's Society for Technical Cooperation (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 emerging countries and small businesses can be improved and sustainability implemented in line with international standards. In more than 130 partner countries, GTZ is supporting 2700 development projects and programs with the aim to improve the living conditions and perspectives of people in developing and transition countries. It 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. A participatory training process is utilized to work to the selection of control technologies. The GTZ program acknowledges that CB models may be too sophisticated for many small enterprises in developing countries; medium and larger enterprises often have more MSDS on site and therefore they have a greater potential for conducting risk assessments using the ILO Toolkit.[59]

Building on the COSHH Essentials approach, countries have also begun to develop their own CB models to address national regulatory requirements and professional approaches. Stoffenmanager (v. 3.0, The Netherlands) is a web-based software tool built for SMEs to assist in working safely with chemical substances. Their CB model factors in an exposure potential through the use of an interactive chemical risk management approach. This model approach was developed in The Netherlands to assist SMEs in assessing, prioritizing, and controlling risks associated with hazardous substances. The tool is based on the COSHH Essentials and a modified version of the Cherrie and Schneider[24] inhalation exposure model.[60]

Stoffenmanager is currently a generic tool that 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 an exposure assessment, involving response to seven questions to determine the chemical's exposure class. The tool automatically calculates a risk score, a relative risk ranking. Thus, an initial assessment of the health risk is completed. Using the tool's risk score, the employer can then calculate the efficacy of various control measures and choose the most effective ones.[61] The Stoffenmanager model has been recently evaluated utilizing targeted field surveys for many dust (i.e., animal feed, flour processing, textile, and construction) and liquid (i.e., solvents for metal, car body repair, and printing) industry exposures in comparison with existing exposure data.[60] This comprehensive validation study initially has found relatively good initial correlation of the non-expert Stoffenmanager score with expert evaluation overall for inhalable dusts ($r_s = 0.83$) and liquids ($r_s = 0.81$). This validation process for the Stoffenmanager model remains an ongoing process and is intended to remain a dynamic process with continual updating.[60]

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.[62] 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 safety phrases (S- phrases) as its basis. Similar to R-phrases, S-phrases also are required by the EU to appear on each label and safety data sheet for hazardous chemicals as part of the classification, packaging, and labeling of dangerous substances provision (Council Directive 67/548/EEC).

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 which include the potential risk and the final risk. These are adjusted for risk based on a judgment of the reliability and appropriateness of the established barriers and/or controls. The risk assessment provides a full risk evaluation of task-based work procedures based on an evaluation of risk for illness related to lungs, internal organs, and skin. KjemiRisk can be considered both a rough risk assessment tool when used by line managers or health and safety 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.(62)

Developing and implementing CB risk assessment/management programs is critically important to many industries that process and market hazardous chemical substances. CB is an invaluable universal tool for assessing and managing these chemical risks. There is an important difference between industries that employ commodity industrial chemicals (e.g., bulk petrochemical, health care, etc.) and those with unique proprietary chemicals (e.g., pharmaceutical, many industrial/commercial products, etc.). Many commodity industrial chemicals are well characterized; therefore, they can be assessed and controlled using existing CB models (COSHH Essentials, etc.). (Note that there is no need to use CB models to manage chemicals for which OELs exist.)

However, industries that process and market unique proprietary chemicals must customize their risk assessment/management CB models for their operations using three essential steps: (1) performing appropriate hazard assessments to classify and communicate hazards; (2) assessing worker exposures in the workplace during specific operations; and (3) communicating, implementing, and verifying the proper control measures. Exposure Control Practices (ECPs)—specific guidance on the control measures—are a valuable tool for managing chemical risks. The ECPs provide a "feedback loop" to ensure that workers are protected and exposures are controlled to the desired levels. ECPs should be based on the Hierarchy of Control principles. Also, they must be verified as part of the exposure assessment program. However, they enable much more robust risk assessment/management than do traditional IH approaches.

Further Model Evolution

Both the UK and ILO CB models focus on the use of bulk chemicals. These models do not cover chemical agents, which are covered by other UK regulations (i.e., asbestos, lead, and pesticides), they also are not intended to address process-generated emissions. These are chemical agent exposures created by the task, or not purchased in bulk, and include construction-related hazards such as silica dust, welding fume, and wood dust exposures as examples. Silica exposures in mining or construction have an excellent track record for existing interventions and practical solutions-based outcomes. These include standardized recommendations and subsequent reduction of exposures relating to the implementation of specified control solutions.(63–65) The UK HSE already has begun to adapt the CB model for broader chemical agents and expansion of the COSHH Essentials approach toward direct control advice. Exposures generated by these processes do not have Risk Phrases and require a different practical approach. The UK HSE has developed a CB process for some of these exposures by directing the user to job-specific control advice sheets relating to initial selected professions such as dry cleaning, hairdressing, and paint spraying.(40,66)

Taking this a step further, the Silica Essentials is also directing users to control advice sheets that are industry and task-based and do not require the additional step of inputting data.(67) Instead, the user selects the control advice directly by activity, avoiding the interim exposure prediction step of the COSHH Essentials model. The Silica Essentials is another CB model that is currently being evaluated in implementation and validation efforts internationally, including in Africa and Latin America.

The stratification of risk that began in the 1970s is now being considered for application in a variety of occupational health, hygiene, and safety professions as well in major industries. The international CB workshops have been an essential element in establishing uniform research agendas for evaluating CB strategies. They also have served to initiate the expansion of chemical-oriented models to best address practical prevention of a broader spectrum of work-related illness, disease, and injury. Topics discussed at these workshops that are beginning to be addressed include the provision of national-level guidance and coordination, pilot projects at the state level, and creation of an Occupational Risk Management (ORM) Toolbox. The ORM Toolbox approach is intended to broaden the CB model to include a more comprehensive exposure control basis for globally common industries, such as construction and agriculture, that require a multidisciplinary approach for chemical, ergonomic, safety, and environmental concerns. Current efforts have begun for the development of a CB model for a Construction Toolbox, addressing these composite, potential exposures by trade and task.(68) To achieve the ORM Toolbox approach, a broader, multidisciplinary framework for trade-related exposures is needed.

Applying the CB model in a multidisciplinary fashion requires some brief consideration of differences between the fundamental approach to IH, ergonomics, and occupational safety. Concepts on exposure and variability of exposure are well developed in the IH profession. These concepts are hardly present in occupational safety. Ergonomics and occupational safety both have a strong focus on design and redesign, which is much less developed in IH. Therefore, as CB models are being developed to address musculoskeletal disorders and occupational injuries, they may find professionals in these specialties well conditioned to this simplified adaptation. While CB strategies like the Silica Essentials are being developed to address locally generated exposures, as in the construction industry, the exposure factors relating to ergonomics are also being evaluated. Another IH to ergonomic comparison is that chemical production involves the development of new products that may never be fully researched and can logarithmically expand the variety of exposure routes and sources for a given worker. In contrast, ergonomics has a finite group of well-researched and defined risk factors and effective programs.[69,70] The ILO Ergonomics Checkpoints document is an example of well-researched and internationally validated models that is being developed as the basis of Ergonomics Toolkits.[71,72] Efforts in The Netherlands have begun to consider the incorporation of occupational safety requirements, with a focus on traumatic injury.[73] Occupational safety is not restricted to chemical safety, but a more general approach is considered, focusing on causes of both major and minor occupational accidents. It has been presented that classifications already exist for various variables of accident causation, which can be viewed as an analogous "banding principle" where safety phrases can be applied in a manner similar to risk phrases. IH practice is devoted to the anticipation and prevention of exposure, however the control of exposure takes place after the central event, the emission of the hazardous substance, has occured. In occupational safety, barriers are active both before and after the central event. Therefore, these barriers, including management factors, have a strong relation with the quality of safety management systems, and these factors are important parameters for risk prevention.[73] The end point of this CB model would not necessarily lead to control advice as much as an identification and implementation of barriers. This barrier banding model would apply these phrases to provide information on the type of hazard of accident scenarios or related situations and will guide the type of precautions needed deal with these scenarios or situations.[74]

Moving back to the roots of the modern CB movement, nanotechnology industries are also finding a limitation in toxicological data in a manner similar to their biological and pharmaceutical counterparts. They also have to achieve a risk management program with an insufficient basis for traditional IH quantitative risk assessment approaches. An important distinction is that they have a longer track record of CB models to work with in developing a control approach. To develop the concept, Maynard[10] has combined the proven effectiveness of CB in controlling exposures in an intensive research and development industry, such as in pharmaceuticals, with the utility of COSHH Essentials model.

A conceptual CB model is presented that offers the same four control approaches of the UK model as stratified by corresponding "impact" and exposure indices. This model proposes combining engineered nanomaterial composition parameters such as shape, size, surface area, and surface activity with their exposure availability in terms of dustiness and amount in use and linking these indices to bands with corresponding control approaches. This nanomaterial CB model, although not developed in practice, is presented similarly to COSHH Essentials in that it is a useful concept that affords a pragmatic approach to exposure control and is considered to be an alternative rather than a substitute to traditional IH risk assessment and control.[10]

DISCUSSION

Underpinning the toxicological basis of the UK approach is the importance of an accurate toxicological rating and hazard band classification by suppliers of chemical substances. Given this critical need for CB models, there is a need to re-evaluate the assignment of R-phrases to chemical substances.[26,42] This process should go beyond work with the COSHH Essentials model and become a central focus for the different CB models available and in development. Significant concerns have been raised about the accuracy of EU classifications of chemical substances.[42] If COSHH Essentials has been designed to be slightly overprotective,[25] then the 15% of evaluated EU classifications that were assigned too low a danger class[42] should be considered a substantial issue to be addressed.

Other confounding issues for the model also require further evaluation. The margins of safety are possibly inadequate for many vapors and some may need to be classified into higher hazard bands.[26,31,38] There is also a variation in hazard band assignment between the COSHH Essentials model and ILO Toolkit.[31,38] In addition to model validation efforts, experts who have written on the CB topic confirm its potential value as a risk assessment and risk management tool in the workplace. They also express caution about the need for systematic, critical evaluation of the approach before widespread adoption.

According to Money,[13] "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 CB 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." Swuste et al.[11] referenced Kromhout[35] 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 lack precision and accuracy in situations where these are required." Tischer and his colleagues[32] 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 data and instead reflects the low degree of confidence generally enjoyed by generic models."

The impetus for the modern movement of CB was the regulatory driven need to address chemical exposures for the majority of the UK work force. COSHH Essentials, the UK model, was created by experts who, with much thought, chose a simplified model to achieve maximum utility in addressing this need. The work of Cherrie and Schneider[24] served to strengthen this decision by showing that a structured approach based on descriptive workplace activities provided significant correlation with exposure measurements. The dissection and examination of this CB model remains an ongoing endeavor. However, its effectiveness in achieving its intended utility is often overlooked as a prime component. Results from the HSE survey on the use and application of the COSHH Essentials model[43] infer utility in the UK. This CB model, however, is also being considered for use in many other countries around the world, including the United States. For this reason the COSHH Essentials model has received additional attention and should receive more to ensure an ongoing critical evaluation to determine whether the model delivers target exposure ranges, offers controls commensurate to exposure potential, is used appropriately, and has improved control of exposure.

In consideration for its implementation, Oldershaw[75] 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, health surveillance as appropriate, etc. A key point is that the approach is not meant to replace exposure measurement, interpretation, substance, and chemical control. These studies and expert comments presented in the literature are not "project stoppers," but rather emphasize the need for collection of data under controlled scenarios to validate the predictions of the model. Underprescription of control could lead to serious injury, while overprescription could lead to significant unnecessary expense, especially for SMEs. Of the two types of error, under-control (recommendation of inadequate level of control) is potentially more serious than over-control. In this model's development the general approach was to be conservative or slightly overprotective.[25]

Internal evaluations of the UK model have shown under-control error for small-scale, dispersed use of solvents and some powder handling operations[32,39] as well as for vapor degreasing and bag filling operations.[41] These results seem to confirm Kromhout's argument[33] that potential misclassification of exposure bands can consequently affect assignment to control bands. Brooke's work predicted this potential; however, this concern essentially was addressed with expectations that the model's scheme and the allocation of hazard bands with R-phrases would be consistently evaluated and improved,[26] but the research has not shown this to date. However, with external evaluation, the COSHH Essentials model has also been found to deliver a significant level of confidence in the target exposure ranges.[32] German BAuA comparisons of the model's outcomes compared with personal exposure monitoring data, in a number of different industries, were well within range for work with solids and medium scale liquids,[32,39] although some under-control error with liquids was found in their work[39] as well as Brooke's.[26]

The ILO Chemical Toolkit, based on COSHH Essentials, has also been shown to indicate more conservative control solutions based on comparisons with the Singapore's SQRA method utilizing personal exposure monitoring data for deriving risk level approaches.[57] Comparisons indicate that, for the majority of the 27 processes selected, the Toolkit equally evaluated or overevaluated the risk relative to the SQRA.[57] Within these validation efforts there has been an acknowledged paucity of data with which to validate CB models.[3,11,13,32,33,41] There is also a limited range of exposure situations with which to compare predictions.[32]

There has also been difficulty in ascertaining reported control classification,[3] proper characterization of specific work parameters, and materials in use[41] for comparison of predicted and actual exposures. The need for health surveillance data/environmental monitoring must be evaluated;[25] particularly when toxicological data are limited.[20] The ongoing need for personal monitoring (air and wipe tests) must be strongly emphasized. The use of the CB models is to complement, not replace the traditional IH approach to risk and exposure assessment. Therefore, personal monitoring is needed to bolster a system that evaluates the effectiveness of controls initially and over time. It will continue to be an essential requirement that ongoing monitoring is needed to detect breaches in containment systems and effectiveness of LEV, even if previously verified.[5]

The work of Jones and Nicas[37,41] has received much attention as its critique of the COSHH Essentials and ILO Toolkit has indicated a high prevalence of control errors[41] and the potential for an inappropriate confidence in the workplace chemical exposure reduction.[37] HSE members responded to their COSHH Essentials evaluation[41] clarifying that their CB model is not intended to predict exposure but rather to identify adequate control approaches.[76] This is a difficult statement to justify in that the exposure prediction step is what separates the COSHH Essentials model from the earlier toxicology-to-control pharmaceutical CB model.

It was also indicated that the article[41] did not actually evaluate the COSHH Essentials as, of the workplace exposures utilized, none of the controls in place were recommended by their CB model. Non-HSE members also responded[77] to these Jones and Nicas articles, noting that the intent of COSHH Essentials is its utility in obtaining and implementing appropriate risk control advice and that user evaluation trials have indicated a higher likelihood of achieving this than if presented in a less accessible or understandable format. Jones and Nicas replied to this commentary[78] indicating that without a recommended prospective study of COSHH Essentials, evaluation of its components is necessary.

While confirming their approach and remaining skepticism of the model's outcomes, they do address their study's limitations in that the variability of engineering control efficiency may also be seen in the high rate of under-control findings. Their margin of safety applications in their assessment of the ILO Toolkit[38] also requires evaluation. Their reliance on safety margins may not be appropriate for validation studies in that their conclusions are heavily dependent on the critical effect's relative toxicity. Higher consequence toxicological outcomes such as cancer require a much larger safety margin than for lower outcomes such as irritation and may, therefore, affect the probability of an under-control finding with more adverse toxicological outcomes.

An important distinction in the development of the UK model is that the current objective of the COSHH Essentials is to achieve exposure levels anywhere in the exposure band, whereas the CIA recommends that exposures should be maintained "as low as reasonably practicable."[19,20] This disconnect with the trade association should be further investigated. Although comparisons to solid chemical exposures have been promising, model validation efforts have shown that it is difficult for researchers to retrospectively evaluate the dustiness of particulates, and it may therefore be difficult for SME managers to do the same.[41] For liquid chemical exposures, under-control error in small-scale solvent applications, although consistent with Brooke's[26] reservations on vapor's equivalency with dusts as in Table III, can in part be attributed to industrial tasks that spread relatively minute quantities over a large surface area, increasing exposure potential. An adjustment or acknowledgement within the control guidance sheets can be made for tasks with these processes; however, the model's weakness with vapors must be further evaluated. In addition, the Regetox approach[12] presented composition by weight for both liquid and solid mixtures in evaluating risks for each harmful component in a workshop that prepares plasticizing mix. Composition by weight is appropriate for solids, but this may skew the estimation of potential risk for liquids as composition should be by molar fraction due to the difference in volatility of various liquid components.

Promising information is just beginning to be put forth in the evaluation of The Netherlands' Stoffenmanager CB model. Their approach has benefited from the ongoing critique of the COSHH Essentials and ILO Chemical Control Toolkit. Critique findings to date have led to Stoffenmanager utilizing exposure assessment prioritization in its banding strategy, which has been derived from the international validation process that includes the international CB workshops.[60,61] Stoffenmanager serves as an excellent example of how dissecting existing models can lead to criteria to be used in developing other exposure control models. Its initial validation study remains an ongoing process, but preliminary information shows that the current generic version of Stoffenmanager indicates its utility as an exposure assessment tool for SME managers and may be an appropriate CB model for use in Tier 1 scenarios relating to REACH. There is now an English version of the generic model that creates opportunities for wider international use and further validation of the model and verification of the effectiveness of its control outcomes. Also in progress is an expansion of this CB model into branch-specific versions that is expected to become a standard in The Netherlands, and the development of a dynamic web-based data exchange module called STEAMBASE (SToffenmanager Exposure and Modeling dataBASE),[60] which may be an important foundation for the prospective studies that are a consensus in CB literature.

Regulatory requirements in the UK were a driver to develop the COSHH Essentials CB model for non-experts to address exposure to chemicals. The model was simplified by design due to the many SME managers under this regulation who do not have easy or affordable access to professional judgment. The pharmaceutical and biological agent exposure control models, the evolutionary predecessors of the modern CB movement, were and are intended for use in Large Enterprises (LE). Due to their size, these industries typically have adequate access to professional expertise and funding for engineering controls and their maintenance. Models relating to pharmaceutical agents, as an example, can therefore be more intricate and achieve greater accuracy, as they are implemented and maintained by trained professionals. The lack of toxicological data and availability of established OELs are the common bases for the creation of both the pharmaceutical agent and chemical exposure control models.

The developers of the COSHH Essentials and the related ILO Chemical Control Toolkit both deliberately chose a less complex model in order to achieve simplicity. The ease-of-use of the UK model has been for the most part achieved for the intent of its development in the UK—use and application by SME managers. However, a key distinction between the models is that the ILO developed its international version for use by non-experts everywhere in the world. This expertise may not be available due to limited funds, such as in the EU or the United States, or due to the relative absence of the IH profession in most industrially developing nations worldwide, affecting LEs as well as SMEs.[79] It was understood in the development of the modern CB models that a practical exposure control tool for non-experts may in practice compromise a level of accuracy when compared with the advice of experts. As important as this is to achieve utility for the intended audience—whether for SMEs, developing countries, or for experts and non-experts alike in the absence of OELs—validation of these models has indeed pointed out areas where this accuracy has been compromised. The focal point then becomes one of perceived risk and the variable levels of acceptability of risk, a perception that varies from country to country, from culture to culture.

The historical basis for the modern CB models was that they were to be used by experts within a research and development environment. The need for this approach was related primarily to the absence of OELs, such as in the biological, pharmaceutical, and now the nanotechnology industries. Validation of these models is complicated in that traditional exposure assessment may not be possible at this time without a proven toxicological basis, as is especially apparent with nanoparticulate.[10] What all these CB models have in common is achieving a level of approachability to what otherwise may remain only in the hands of those with access to expert judgment. They also share a certain acceptance of risk and inaccuracy. Adaptation of the existing models beyond bulk chemical use has been assisted by this cumulative CB discussion in that developers can learn from still ongoing evaluations and benefit from a growing acceptability of simplicity in achieving exposure reduction. The practical nature of the silica, ergonomics, and injury prevention CB model approaches indicates that they are likely to succeed, although not with the same rigor of validation and evaluation that should be given to all CB models. In developing multidisciplinary CB strategies it has become apparent that involvement of stakeholders is helpful in defining minimum performance standards, whether required by regulation or by circumstance.

CONCLUSION

Further research remains a requirement for all CB models. This includes further internal validation of CB model components, broader external validation of the model predictions when compared with expert interventions, and especially the need for operational analysis of the model as implemented to achieve intended outcomes. A prospective research process therefore remains essential to achieve an understanding of the implications of the model as applied and how this correlates to its overall effectiveness for its target group. This will assist in addressing the remaining questions as to how control recommendations are being implemented and maintained and whether they are achieving the intended exposure reduction. The lack of this information has led many to question the overall effectiveness of CB models in that they have knowingly chosen simplicity at the expense of accuracy and, therefore, protection of the worker. This research needs to be performed and the results folded into an improvement process for CB models, which must include continual re-evaluation of R-phrases and GHS Hazard Statements, in order to scientifically address these questions. In addition, further field studies are also vital to this research as they are necessary for providing essential validation and verification data, which in turn will improve our practical understanding of the strengths and weaknesses of each of the models. In the absence of this information, the CB models as currently available are best used when OELs do not exist or as initial risk assessment screening tools that at some level include expert input and traditional IH monitoring.

It seems that lost in these scientific validation discussions are the billions of workers who do not have access to expert advice. When further research is performed it must not stop short at the dissection of models. It must use the lessons learned from the process to build a better model that does have a place in the hands of non-experts. CB models are therefore, in essence, an opportunity to simplify the best of scientific information into a format that is accessible to the multitudes. Expert IH advice in practice is expensive and is nonexistent in many countries, rendering it inaccessible to so many. This fact should not be used as an excuse to apply unvalidated control models blindly, but rather to serve as an impetus to expand the reach of this expertise and to develop it where it does not exist. With this in mind, the modern CB movement should continue to seek the finest technical expertise to make the models as *good* as possible. Seeking perfection will only ensure that the prevention of work-related disorders will not be achieved for the majority of the world's work force.

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