IEH Institute of Environment and Health

ICMM International Council on Mining & Metals

Towards a Harmonized Approach to Setting Occupational Exposure Limits

Report of an ICMM-sponsored workshop, London, 9–11th November 2005

May 2006

Contents

Foreword

Operations in the mining, minerals and metal processing industries have the potential to bring workers into contact with harmful materials and agents. Having clear, science-based exposure limits for all potential workplace materials and agents is an important element in the effective control of exposures in the workplace.

Generally, occupational exposure limits are set by government and are embodied in mining and workplace safety laws and regulations. Many companies have their internal corporate standards which are usually equal to, or stricter than the respective government-set limits. Confusingly, both for the industry and its workforce, there are instances where occupational exposure limits vary between jurisdictions because of differences in the approach taken to setting the limits. These differences include the selection and interpretation of data, the approach to risk assessment and the risk acceptance criteria used in the risk assessments.

ICMM believes there is benefit in adopting a consistent approach and methodology in the review of occupational exposure limits (OELs). The central component of the proposed harmonized approach is to promote a systematic method of evaluating, assessing and agreeing data and evidence, as well as a standardized way to assess the risks of exposures and the subsequent health effects. We also want to see recognition that risk acceptance criteria will vary from place to place depending on the cultural acceptance of risk, but it is important that the development of such criteria is based on common principles. Harmonization of the way OELs are set and the introduction of greater transparency in the process should be to the benefit of everyone involved.

For ICMM to achieve these aims we recognize the need for dialogue and understanding among a wide range of stakeholders, companies and territories. To begin the process, we convened an international workshop in London in November 2005 which was attended by a limited number of regulatory scientists, academics and industry representatives. This report summarises the main findings of the workshop which provided opportunity for reflection on ICMM's aims and generated advice and recommendations for the way forward.

Martin Webb
BHP Billiton, and chairman of the ICMM Occupational Exposure Limits Working Group

1. Introduction

Occupational exposure limits (OELs) have been used by governments and their regulatory bodies as a means of controlling exposure of workers to harmful substances or other agents since the turn of the 20th century. The earliest OELs include those established in Germany in 1883, the standard for quartz set in South African gold mines in 1916, and the setting of OELs for 33 substances by the US Bureau of Mines in 1921.

More recently, the threshold limit value (TLV) approach developed by the ACGIH in the mid-1940s has become, perhaps, the most influential throughout the world, with its assessments and standards being either directly accepted or used as a basis for consideration by many authorities throughout the world. Nonetheless, despite the admitted influence of the ACGIH, there is no uniform approach to the methodology of setting OELs, nor is there international acceptance of either data packages, scientific assessments of data or of the actual levels established by one body or by others. This is perhaps not surprising given that OELs may be suggested or legally established by many different groups, including: governmental bodies or agencies; independent scientists on advisory committees to government; professional groups of practitioners; and independent academic groups of varying status. As a result, there may be considerable duplication of efforts to collect, collate and assess datasets for particular substances, and considerable variations can occur in both the interpretation of the available data or the OEL numerical values established by the various bodies and governments world-wide. Such variations can pose considerable operational challenges to many areas of industry, particularly for those organizations operating on the global scale.

1.1 Background information on the process of establishing OELs

When considering the purpose of setting OELs it is essential to appreciate that, unlike some other regulatory standards, OELs are not intended to protect all individuals within the general population, rather they are meant to protect the majority of the workforce and therefore use phrases such as 'most' or 'nearly all'. Various types of standard have been developed to address acute health effects (by the use of short-term exposure limits (STELs) and ceiling values) and effects on health following chronic exposures (through use of time weighted averages, e.g. 8hr TWA). Most OELs are intended to not just provide protection for the individual during their working life but to also address effects during post-working life and in their offspring. Most approaches now distinguish between the so-called 'threshold' and 'non-threshold' health effects.

The evidence base used when developing health-based OELs draws upon a wide range of data types. These include human data derived from case reports, volunteer study (workers or others), epidemiology investigations on workers health (which may be of variable quality) and, increasingly, studies using biomarkers of exposure or biological effect. Experimental studies are also considered, and may include acute or repeated exposure of animals, in vitro studies and by analogy to similar chemicals using structure activity relationship (SAR) models.

Information on actual or predicted exposures may be derived from industrial experience using static or personal sampling, from comparisons of exposed workers and controls, and by consideration of the use of personal protection and the state of technology in that industry. It has been noted that the amounts and quality of data may be highly variable (e.g. exposure data may vary from occasional grab samples to systematic monitoring).

There are currently a number of significant scientific challenges that face standards setting. These include: the variability and robustness of available data; uncertainties as to the use of geometric or arithmetic means as the most representative metric for exposure; in the case of metals, the significance of speciation for health effects; and differences in the approach to substances with 'non-threshold' effects, such as mutagens, some carcinogens, and respiratory sensitisers – where there is debate as to the

importance of peak versus steady state exposure with regard to induction or elicitation of effect. There are also differences in approaches to the selection of critical effect end-points and in application of uncertainty factors, which has implications for the setting of OELs. Often, understanding the rationale for the decisions taken may be difficult in that these may not be clearly stated in the documentation published. The complexity of the situation is further increased by national differences in the legal status of OELs and who, and to what level, is protection intended to be provided under law. Even subsequent to the establishment of a health-based value, the eventual OEL set may be further influenced by other factors relating to risk management; for example, socio-economic considerations (cost versus risk) and practical constraints (can it be controlled?).

The approaches to such aspects may differ significantly between jurisdictions, resulting in a further source of potential variation in OEL values. As a thought piece, the following theoretical scheme for the setting of OELs was presented at the workshop.

Simplified generalized approach for OEL setting

The following elements were suggested as encapsulating, in a simplified manner, the essential stages that should be undertaken when establishing an OEL:

Derivation of draft 'health-based' value

- Comprehensive literature review according to current quality criteria
- Selection of critical health end-point(s), along with understanding the threshold/non-threshold nature and dose-response relationships of the effect(s)
- Selection of key studies for OEL setting
- Understanding of the exposure data and information relevant to above two steps
- Application of appropriate, explained uncertainty factors to derive an initial 'draft' OEL

Development of final OEL

- Identification, application and explanation of non-scientific (risk management) influences on the final development of the OEL
- Discussion on the availability of appropriate sampling technology
- Full documentation and publication of all steps and assumptions used in the OEL derivation

1.2 The ICMM initiative and this workshop

In response to the operational challenges faced by industry with regard to differences in the approaches taken to establishing OELs and the potential ensuing variation in the numerical values, the International Council on Mining and Metals (ICMM) has launched an initiative to investigate and, if found to be broadly acceptable, to promote the development of a harmonized approach to setting OELs.

Harmonization of approaches to OEL setting is viewed by ICMM as an important element in promoting a sustainable and governance-based approach to minimizing the potential for occupational disease internationally. Key elements of the approach include:

- the development of a common definition and understanding of an OEL
- use of sound science as a basis for establishment of an OEL;
- consistency of application of risk assessment methodology;
- recognition of the importance of socio-economic impact and what is technically achievable; and
- processes that are totally open and transparent to all stakeholders.

As an early step in assessing the scope for development and implementation of such a harmonized approach, the ICMM sponsored a 3-day workshop in London from the 9th to 11th November 2005. The working papers for the workshop, entitled *Occupational Exposure Limits: An evidence-based, Harmonized Approach*, were prepared by scientists then located at the MRC-Institute for Environment and Health, in the UK. In addition, a short paper 'Towards a harmonized approach to setting OELs' by Linda Shuker and Len Levy was published in the *Occupational Health Review* journal, Issue 117 Sept/Oct 2005. Prof Levy is now located at the recently re-established Institute of Environment and Health (IEH) at Cranfield University and he and two other IEH scientists acted as rapporteurs for the workshop. The meeting was attended by invited experts from relevant government bodies, academics with extensive experience in standard setting and independent consultants. These individuals acted throughout as independent experts and not as representatives of their particular organizations. A number of industry representatives with relevant occupational health or hygiene experience also attended.

The program for the workshop (see Annex 1) comprised an initial series of presentations intended to establish the context for, and objectives of, the workshop followed by consideration of a series of prepared questions (Annex 2) by each of three subgroups. Subsequently, the main points arising from the discussions of each subgroup were presented, and further discussed, in plenary sessions. Participants who attended the workshop are detailed in Annex 3.

This report, prepared by the workshop rapporteurs, summarises the discussions that occurred during the course of the meeting, focusing particularly on the output of the plenary sessions, and identifies the conclusions reached and suggestions made for the future progression of the ICMM initiative. As such, this report is not intended as a consensus report of the workshop, and does not necessarily represent the views or opinions of individual participants at the workshop.

2. Summaries from discussions in Sessions 1 to 3

Session 1

The aim of Session 1 was to generate a useful discussion on approaches to identifying substances of concern, how research and review methods should be focused on priority substances of concern and finally, how the quality and applicability of data should be used in OEL setting procedures. The following questions were specifically addressed in the three breakout groups:

- How do we (all stakeholders) identify who is concerned about which substances?
- How do we validate concerns?
- How do we gain agreement on priorities?
- How do we identify gaps in knowledge?
- How do we decide the substances and agents on which research and effort are directed?
- How should the direction of research effort be directed?
- How do we bridge the gaps in research capacities?
- How do we time the process of review to meet the needs of all stakeholders?
- How do we pool and coordinate resources to meet our common objectives?
- What guidelines on data validation already exist?
- What guidelines exist for establishing the minimum data requirements for setting OELs?
- How should animal study data be interpreted and ranked against human data?
- How should epidemiological data with confounding elements be considered?
- How do we acknowledge the uncertainty of data in the setting of an OEL?

The session opened with a brief discussion on the various principal bodies active in setting OELs, and their approaches. It was noted that, of the six major standard setting organizations that are most active currently in the assessment and derivation of OELs, five were located within the EU (and the other in the US). While possibly reflecting the availability of resources and historic economic profile, it was noted that, particularly for the mining industry, there is a significant geographic mismatch between the standard setting activity and the areas of industrial activity.

When considering the scale of the task facing the regulatory bodies and industry alike in establishing a suitable framework to control the occupational use of chemicals, attention was drawn to estimates that the number of chemicals that may be (or have been) used within the EU could be up to 100,000. It was noted, however, that European authorities have only undertaken formal risk assessments on a few hundred while, at the national level, even the long standing German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) has evaluated only about 900. Furthermore, it was apparent that there are a number of major challenges facing the standard setters, such as setting standards for metals (in particular regarding the potential significance of speciation on toxicity, the multiplicity of sources and the role of some metals as essential elements), the assessment of the toxicity of mixtures, and the challenges associated with the increasing introduction of novel nanomaterials. Also, the requirements of the proposed European chemical policy, REACH, will make further demands on the available scientific expertise. It is therefore expected that there will be a problem for the foreseeable future in supporting the necessary underpinning activities because of the scarcity of adequate regulatory and scientific resource and expertise.

There were noted to be good formal working relationships and informal information flow between the various standard setting bodies (e.g. MAK and ACGIH; EU national groups and SCOEL). It was however, recognized that, at present, there exists no effective system to allow joint acceptance of data or opinion, nor for pooling of resources or establishing inter-authority agreements on priorities. In particular, the difficulty in prioritizing chemicals for consideration by the various bodies is compounded by the absence of formalized systems to advise regulators of substances of concern. At present, the standard setting bodies may be advised of a new chemical or a potential change in the level of concern by industry or unions or through political or media interest, and there is the potential for confrontational situations to develop. In addition, in many cases standard setting bodies may be unwilling or unable to set a standard for a chemical because of lack of adequate data, and when production or use of a chemical first occurs there may be a particular scarcity of data available. There is thus a clear need for development of improved systems to prioritise chemicals for

review, and for promoting sharing of data and information between the various standard setting bodies. However, the extent to which such practices can be achieved will in large part depend on the willingness of standard-setting bodies to co-operate and to attempt to resolve scientific differences of opinion.

While many standard-setting bodies now identify gaps in knowledge in their more recently published evaluations and opinions, this may not be the case for many OELs of long-standing. There is also no clear system for translating identified data gaps into the implementation of further research or data gathering by industry or other parties and, furthermore, at least some of the standard-setting bodies are averse to entering into a dialogue with industry regarding the optimum design of study protocols to address the data gaps. Guidelines on the validation and acceptability of data are also not well developed, with standard-setting bodies taking a pragmatic approach to their review of datasets for individual chemicals based upon the extent of data available, with emphasis generally being given to good quality human data over experimental findings.

While harmonization of guidelines would be desirable, it may not be a practical goal. It was, however, suggested that it would be helpful were the standard-setting bodies to publish an indication of the strength and robustness of the exposure and health effects data used in an assessment to inform on the level of uncertainty that may surround a resulting OEL. In response, it was however noted that the uncertainty of the no-observed-adverse-effect level (NOAEL) and other factors used in establishing an OEL is generally reflected by the size of uncertainty factor used to derive the proposed health-based limit. The choice of uncertainty factor is often subjective, based on expert judgment, and it was noted that this process should be clear and transparent. On a more general note, it was suggested that where a new material or substance is used in the workplace, there should be a formal requirement to consider the need for a health monitoring program.

The limitations in the current systems pose a considerable challenge to industry as it attempts to ensure the safety of its employees when introducing new substances or technologies. Companies currently tend to attempt to address such problems through establishing in-house exposure limits based upon the available information and their own scientific and technical expertise. However, while this may be possible for large companies, small and medium sized companies are unlikely to be able to address the issues adequately, and individual companies are generally unwilling to share information, often because of concerns regarding legal liability.

The current situation can thus lead to a dichotomy of views, with the standard-setting bodies striving for the most scientifically valid assessment of the hazard posed by a chemical in order to determine an authoritative and well-validated OEL, while the focus for industry is more towards establishing a dynamic ‘best practice’ approach to facilitate rapid introduction of technological changes.

Session 2

The aim of Session 2 was to generate discussion on approaches to setting OELs for threshold and non-threshold substances, how to undertake a harmonized and transparent risk assessment and how to harmonize risk acceptance criteria across different jurisdictions. The following questions were specifically addressed in the three breakout groups:

- What drives the need for differentiating between 'threshold' and 'non-threshold' substances in relation to the setting of OELs?
- How are 'non-threshold' substances identified?
- How can meaningful OELs be established for 'non-threshold' substances?
- What is/are the current approach(es) for setting OELs for 'non-threshold' substances and what is the argument for change?
- What risk assessment methodologies are currently used?
- Are there substantive differences between methodologies?
- Is there a need to vary the methodology depending on the magnitude of the potential health impacts?
- How can we make the risk assessment methodologies transparent and understandable to all stakeholders?
- Should priority always be given to establishing health-based OELs rather than using those derived from non-health-based criteria?
- How are risk acceptance criteria described?
- How do different jurisdictions set their risk acceptance criteria?
- How can risk acceptance criteria be made transparent to stakeholders?
- How can the impact of risk acceptance criteria on OELs be assessed and validated?

There was considerable discussion about the current dichotomous approach to categorizing substances as possessing 'threshold' or 'non-threshold' mechanisms of toxicity. Generally those with genotoxic or sensitizing potential are regarded, and regulated, as exerting non-threshold effects for which no safe level of exposure can be established. It was, however, noted that the 'non-threshold' concept was increasingly being challenged through increasing scientific knowledge of the underlying mechanisms of toxicity. These considerations have yet to be generally accepted within a regulatory context, although there are some examples where it has already been possible to establish standards; for example, styrene where a German MAK was established based upon an extrapolation to the toxic effect of endogenous nitric oxide production. There also remain problems for standard setters and regulators as to the appropriateness of the various linear and non-linear dose-effect models that have been published, and the preferred approach currently differ on a body-to-body and national basis. It was suggested that greater use of the benchmark dose approach coupled with adoption of 'acceptable risk' levels might prove of value for 'non-threshold' substances (i.e. focus on risk-based rather than health-based solutions). It was, however, noted that any OEL established should be associated with subsequent detailed workplace monitoring to confirm the suitability of the chosen level a regard to health impact. In the process of establishing a health-based OEL, there is limited or no risk acceptance criterion applied, although the final OEL that is used by industry may be modified from the health-based value suggested, as a result of later stages of the process which involve risk management and socio-economic considerations. In situations where it is not possible to establish a definitive health-based limit, some countries prefer a risk-based approach while other attempt to define 'best practice' based levels. It was highlighted that there was a significant difference implied in the use of terms such as 'best', 'good' and 'reasonable' when considering operational practices by industry.

It was noted that even within Europe there were significant differences in approach and practice and that, while the ideal, gaining harmonization of practices would be a considerable challenge. In any event, whatever the approach taken, it was considered essential that industry undertake good monitoring studies and ensure that the resultant data, including negative findings, are published in the peer-reviewed literature. The historic difficulties with gaining journal acceptance of negative studies was raised, however it was felt that in recent years the situation had improved somewhat. Nonetheless it was considered essential that the studies conducted were of sufficient size and robustness to provide confidence in the predictive power of the study. A specific gap in our knowledge of the longer-term effects on the health for retired workers in the developing nations was also identified as a high priority area for further research. Some from industry commented that, in some circumstances, it appeared that industry-derived data were considered suspect by regulatory bodies and could even be used as a tool to criticize industry. Such institutionalized-attitudes would, not

surprisingly, have a negative effect on industry's willingness to undertake or sponsor this much needed research. A suggestion was made that there may be a need to establish an organization as a 'clearing house' for collating and integrating data from companies that could facilitate the undertaking of much more powerful studies than would otherwise be possible.

The need for greater transparency in the process of establishing an OEL and for provision of adequate guidance on risk assessment methodologies was again emphasized. An area considered to warrant particular attention was the nature and appropriateness of uncertainty factors, although it was pointed out that a number of papers and articles on this aspect had recently been published. In general, the size of uncertainty factor applied to a 'no-effect level' depended on the nature and severity of the effect under consideration, and the robustness of the dataset on which the assessment was based. It was, however, admitted that there were divergent views and approaches between standard-setting bodies, partly reflecting differences in the legal basis and acceptable tolerance levels between jurisdictions. Thus, while establishment of an OEL by a standard-setting body implied a certain degree of protection, differences in the degree of protection required to meet legislation differed between jurisdictions and OEL values would be expected to differ accordingly even if there was general agreement as to the toxicity profile of the particular substance. In any event, moves towards greater transparency and explanation in the publications of standard-setting bodies were still to be welcomed.

Session 3

The aim of Session 3 was to generate discussion on measurement techniques for workplace exposures in relation to OEL setting, the introduction of acceptable compliance criteria and the harmonization of exposure and health impact assessment methodologies across different jurisdictions. The following questions were specifically addressed in the three breakout groups:

- How do we ensure that the technical capacity to measure exposures is considered in the setting of OELs?
- How do you effectively analyse 'censored data'?
- What does 'compliance' with OELs really require – 100% of the people 100% of the time – or something less?
- How should different work regimes be approached relative to averaging time?
- How should we approach consideration of exposures to mixtures?
- How can we achieve consistency in exposure and health impact assessments?
- How can we collect and analyse the data?
- How can we provide effective feedback to all stakeholders?

The problem of deriving meaningful retrospective exposure information was discussed and the difficulties in measuring adequate exposure data were acknowledged. Problems regarding the selection of appropriate size fractions, metrics and sampling devices (be they for personal or static sampling) to use when assessing particles and dusts were discussed. It was suggested that future sampling campaigns should adopt the practices recommended in ISO7708. It was also emphasized that, in order to be able to ensure comparability/ interpretability of exposure data across time, it was essential that any change in the technology used to measure exposures should be adequately validated before use and that the new and previously-used systems should be run in parallel for a period to demonstrate comparability.

A specific question was raised as to the approach that should be taken when analysing censored data (e.g. the non-normal distribution that arises where OELs were close to the level of detection, and subsequent sampling showed many of the samples to be at levels below the detection limit). It was stated that this can cause problems with demonstrating compliance in 'real world' situations. In response, it was noted that there are simple statistical techniques available that can be applied

to such datasets, and that ultimately the objective should be to engineer to achieve a 'zero harm' position.

This led to further discussion on the differences in compliance requirements between jurisdictions. For example, the UK's HSE adopts a very pragmatic approach, seeking to establish that 85-90% of the exposures values fall below the OEL. So, although they may allow excursions, they will focus on the process, with the emphasis being on ensuring consistent good practice.

When considering the question of the practicality of measuring and monitoring worker exposure from health-based OELs established at very low values below those that current technology can accurately detect, a difference in opinion was evident between some experts and industry representatives. These experts regarded setting such values as a useful tool to drive the technological development of analytical techniques to enable measurement to occur. Others adopted a more pragmatic position, questioning the value of establishing limits that are too low to be accurately measured, and suggesting that in such situations studies should first be conducted on worker populations to identify if there was any evidence that exposure to the substance at measurable levels associated with any evidence of an effect on health.

One issue identified with regard to the practical application of published OELs in real world situations, was the range of work patterns workers may actually undertake compared with the published OEL values (frequently expressed in terms of 8hr TWA). This was identified as requiring expert judgement on a case-by-case basis, since consideration would need to be given to the nature of the toxic or health endpoint of concern, and the mechanism of toxicity and its toxicodynamics and toxicokinetics. Thus, while for noise averaging of levels over a week is a generally acceptable approach, for other stressors, such as chemical insults, the critical effect may occur over a much shorter time frame. It was, however, recognized that inclusion of clear statements as to the nature of the health concerns in Criteria Documents or with published OELs would be of great assistance to occupational hygienists and health and safety practitioners. Mention was also made of the real world problems facing industry where they generally have to demonstrate compliance in situations involving exposure to complex mixtures. It was suggested that, provided that consideration of the effect on which the OELs were based supports this (i.e. common endpoints/mechanisms involved), then application of the inverse additive rule is generally adequate.

There was a call for the development of harmonized guidelines for use in exposure assessments, to facilitate the conduct of high quality prospective epidemiological studies and to improve the interpretation of health surveillance data. It was noted that such guidelines would probably differ from what would be needed for monitoring for compliance, and it was suggested that they may even have to be substance/effect specific. A recognized weakness in many studies undertaken to date was also noted to be the lack of accurate exposure and health baselines. It was suggested that those planning such studies (which may include companies, trade associations or statutory bodies) should seek to consult the standard-setting bodies, regulators and workers, in particular with regard to identifying the gaps in knowledge that need to be addressed; these might include biomarkers, health outcomes and/or exposure assessments. However, the willingness of the various parties to contribute to such discussions may currently be variable. It was also considered that, for industry to be persuaded of the need to conduct such prospective studies, there must be a willingness on the part of the regulatory and standard setting bodies to re-evaluate the data and review the OEL.

A number of drivers for identifying the need for post-OEL validation were suggested: good practice; where there is a suspicion that the OEL may not be stringent enough to prevent adverse health effects; where an OEL in one jurisdiction is viewed as too stringent and costly to implement and without any apparent health benefit compared to that of another jurisdiction; and where legislation requires exposure assessment and health monitoring.

3. Conclusions arising from Session 4 and recommendations for future progression of the initiative

The following questions were discussed within the breakout groups:

- How can industry best contribute to the harmonization of OEL setting?
- How can the industry best provide an ongoing contribution to the process?
- What are the key issues and how should they be addressed?
- Are there any existing industry initiatives or models from which we can learn?
- Who are the key stakeholders and how should they be engaged?
- What is the next key step?

The workshop was shown to be a suitable vehicle to facilitate the opening of dialogue between the various stakeholders who attended, and allowed for a free and open exchange of views between individuals variously drawn from industry, regulators and academic circles. Discussions over the course of the workshop confirmed that there are considerable differences between the approaches to establishing, and the values set for, OELs across the world. However, there was general recognition of the potential benefits to stakeholders from greater harmonization of approaches to establishing OELs.

It was noted that it is important to appreciate that harmonization does not mean that all standard-setting bodies must, of necessity, produce identical assessments or standards. However, it will require that the processes and decisions reached when developing standards must be sufficiently transparent to enable understanding of any differences. The potential benefits of harmonization identified include: increased efficiency of utilization of scarce resources through sharing of expertise and costs; promotion of a higher uniform quality; and greater confidence in the robustness of the OELs established among the regulatory community, industry and the labour force. Furthermore, provided that there is adequate compliance and enforcement world-wide, such harmonization would be expected to act against 'social dumping' and lead to sharing of best practice, and thereby increase the level of worker protection world-wide.

It was, however, apparent that achieving harmonization may prove difficult, partly due to the varying remits and underlying philosophies of standard-setting bodies, and also because of differences in scientific belief and approaches that exist world-wide. In particular, it was acknowledged that, at least in the opinion of some regulatory scientists, it is essential that the scientific process of deriving recommendations for health-based standards should be completely divorced from any other considerations. That is to say that other aspects (such as: the need by those involved in industry to have rapid access to advice on appropriate standards, even if only based on provisional assessments; the practicality of measurement or achievability of an OEL value; and cost-benefit considerations) should only be considered downstream of the initial scientific considerations of a health-based value. A further limitation with regard to efficient utilization of the available database is a possible reluctance by some bodies to use datasets prepared by other bodies, with the preference being to derive their own dataset for review and assessment.

Encouragingly, the workshop identified that regulators and their academic advisors would strongly support an increased role for industry in providing data and information on worker exposure and health, and it was particularly evident that the process of moving towards harmonization offers a unique opportunity to industry for enhancing their interactions with regulators and other stakeholders within an open and transparent framework.
It was also noted that standard-setting bodies are frequently under intense pressure because of their limited resources and, while it was considered inappropriate for industry to provide resources or financial support directly, any pressure that industry and other stakeholders may be able to exert at a political or governmental level would be welcome, in particular to increase awareness of the importance of the activities undertaken by these standard-setting bodies, and thereby help to improve the level of resource support provided from public funds.

In order to progress the current initiative further, it was apparent that it will be necessary to ensure the broadest possible stakeholder involvement, including participation of interest groups that were not represented at this particular meeting. In addition, such expansion in the scope of activities might best be served through seeking the active involvement of a major international organization to host future fora for discussion (examples of suitable bodies suggested include the WHO, ACGIH and ICOH).

It was also considered important, in order for industry to be perceived as inclusive, that ICMM promulgate awareness of the topic of harmonization and gains the active support of a broad swathe of other industries, for example through elicitation of support from organizations such as International Council of Chemical Associations (ICCA), American Chemical Council (ACC) and European Chemical Industry Council (CEFIC). However, a potential barrier to gaining acceptance of an increased role for industry in developing harmonized approaches to OEL setting by other stakeholders, was the generalization – to the wider body of industry – of adverse impressions gained when some sections of industry take inappropriate, overly-defensive actions to block or delay perceived threats to their activities as, for example, in the case of proposed tightening of safety regulations. The ICMM clearly has an important role in educating the wider industry community in the need for transparency and openness.

In addition, there appears to be an important role for ICMM and similar organizations in facilitating, and contributing to, training opportunities with regard to OEL setting.

Annex 1
Workshop program

<table>
<tr><th>Time</th><th colspan="3">Day 1</th><th colspan="3">Day 2</th><th colspan="3">Day 3</th></tr>
<tr><td>0900 – 0930 hrs</td><td colspan="3" rowspan="2"></td><td rowspan="3">Group 1
– Issue 4</td><td rowspan="3">Group 2
– Issue 5</td><td rowspan="3">Group 3
– Issue 6</td><td colspan="3">Plenary – The New Task</td></tr>
<tr><td>0930 – 1000 hrs</td><td rowspan="2">Group 1
– The Path Forward</td><td rowspan="2">Group 2
– The Path Forward</td><td rowspan="2">Group 3
– The Path Forward</td></tr>
<tr><td>1000 – 1030 hrs</td><td colspan="3">Registration - Coffee</td></tr>
<tr><td>1030 – 1100 hrs</td><td colspan="3" rowspan="3">Establishing the Context –
The Challenge Faced By The Mining and Metals Industry</td><td colspan="3">Morning Tea</td><td colspan="3">Morning Tea</td></tr>
<tr><td>1100 – 1130 hrs</td><td colspan="3" rowspan="2">Plenary with each Group Reporting on Outcomes</td><td colspan="3" rowspan="2">Plenary with each Group Reporting on Outcomes</td></tr>
<tr><td>1130 – 1200 hrs</td></tr>
<tr><td>1200 – 1230 hrs</td><td colspan="3">Facilitator Overview</td><td colspan="3">Lunch</td><td colspan="3">Chairman's Close</td></tr>
<tr><td>1230 – 1300 hrs</td><td colspan="3" rowspan="2">Lunch</td><td colspan="3" rowspan="2">Lunch</td><td colspan="3" rowspan="2">Lunch</td></tr>
<tr><td>1300 – 1330 hrs</td></tr>
<tr><td>1330 – 1400 hrs</td><td rowspan="4">Group 1
– Issue 1</td><td rowspan="4">Group 2
– Issue 2</td><td rowspan="4">Group 3
– Issue 3</td><td rowspan="4">Group 1
– Issue 7</td><td rowspan="4">Group 1
– Issue 8</td><td rowspan="4">Group 1
– Issue 9</td><td colspan="3" rowspan="6"></td></tr>
<tr><td>1400 – 1430 hrs</td></tr>
<tr><td>1430 – 1500 hrs</td></tr>
<tr><td>1500 – 1530 hrs</td></tr>
<tr><td>1530 – 1600 hrs</td><td colspan="3">Afternoon Tea</td><td colspan="3">Afternoon Tea</td></tr>
<tr><td>1600 – 1630 hrs</td><td colspan="3" rowspan="2">Plenary with each Group Reporting on Outcomes</td><td colspan="3" rowspan="2">Plenary with each Group Reporting on Outcomes</td></tr>
<tr><td>1630 – 1700 hrs</td></tr>
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Annex 2
Questions posed to Working Groups in Sessions 1 to 3

Session 1
(Day 1, 1330-1530)

Group 1 – Approaches to identifying substances of concern

Problem Statement – There is a significant number of substances in the mining and metals industry for which there are concerns over the absence, currency or relevancy of the OEL.

- How do we (all stakeholders) identify who is concerned about what?
- How do we identify gaps in knowledge?
- How do we validate concerns?
- How do we gain agreement on priorities?

Group 2 – Focusing research and review efforts to substances of concern

Problem Statement – There are limited resources and capacity available to undertake research into OELs.

- How do we decide the substances and agents on which research and effort are directed?
- How should the direction of research effort be directed?
- How do we bridge the gaps in research capacities?
- How do we time the process of review to meet the needs of all stakeholders?
- How do we pool and coordinate resources to meet our common objectives?

Group 3 – Data assessment and validation

Problem Statement – There is no commonly agreed means of assessing the quality and applicability of data used to set OELs.

- What guidelines on data validation already exist?
- What guidelines exist for establishing the minimum data requirements for setting OELs?
- How should animal study data be interpreted and ranked against human data?
- How should epidemiological data with confounding elements be considered?
- How do we acknowledge the uncertainty of data in the setting of an OEL?

Session 2
(Day 2, 0900-1100)

Group 1 – Setting OELs for non-threshold substances.

Problem Statement – The continued exposure to 'non-threshold' substances in the mining industry is unavoidable.

- How are 'non-threshold' substances identified?
- What drives the need for differentiating between 'threshold' and 'non-threshold' substances in relation to the setting of OELs?
- How can meaningful OELs be established for 'non-threshold' substances?
- What is the current approach for setting OELs for 'non-threshold' substances and what is the argument for change?

Group 2 – A harmonized and transparent risk assessment methodology

Problem Statement – The risk assessment methodologies used in setting OELs are often unclear to stakeholders.

- What risk assessment methodologies are currently used?
- Are there substantive differences between methodologies?
- Is there a need to vary the methodology depending on the magnitude of the potential health impacts?
- How can we make the risk assessment methodologies transparent and understandable to all stakeholders?
- Should priority always be given to establishing health-based OELs rather than using those derived from non-health-based criteria?

Group 3 – Jurisdiction-set risk acceptance criteria

Problem Statement – Risk acceptance criteria vary across jurisdictions and are not always transparent to stakeholders.

- How are risk acceptance criteria described?
- How do different jurisdictions set their risk acceptance criteria?
- How can risk acceptance criteria be made transparent to stakeholders?
- How can the impact of risk acceptance criteria on OELs be assessed and validated?

Session 3

(Day 2, 1330-1530)

Group 1 – OELs and measurement techniques

Problem Statement – OELs set close to, or below, the capacity to measure exposures in the workplace are problematic.

- How do we ensure that the technical capacity to measure exposures is considered in the setting of OELs?
- How do you effectively analyse 'censored data'?

Group 2 – Compliance criteria

Problem Statement – There is no common definition of 'compliance' to OELs and regulators vary in their assessment of compliance.

- What does 'compliance' with OELs really require – 100% of people 100% of time – or something else?
- How should different work regimes be approached relative to averaging time?
- How should we approach consideration of exposures to mixtures?

Group 3 – Harmonized exposure and health impact assessment methodologies

Problem Statement – there is no ongoing process for validating OELs. Exposure and health impact assessment methodologies are not consistent across jurisdictions.

- How can we achieve consistency in exposure and health impact assessments?
- How can we collect and analyse the data?
- How can we provide effective feedback to all stakeholders?

Annex 3
Workshop participants

Individual experts attended the workshop in their own right and not as representatives of the Organization or Committee with which they are affiliated.

Dr Patabendi Abeytunga
Dr John Atherton (ICMM Secretariat)
Ms Elanor Ball
Dr Audrey Banyini
Dr Dave Barnes
Dr Rodger Battersby
Dr Ben Davies (ICMM Secretariat)
Prof Vito Foa
Dr Frank Fox
Dr Richard Gaunt
Dr Terry Gordon
Prof Helmut Greim
Dr Alicia Hiuci-Montagud
Mr Philip Holmes (IEH)
Ms Kathryn James (IEH)
Prof Gunnar Johanson
Prof Len Levy (IEH)
Dr Adriana Oller
Dr Jimmy Perkins
Dr Alison Searl
Mr Martin Webb (Chairman)
Mr Tim White

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