Report: IOHA 2018 - 8th International Control Banding Workshop – Control Banding and beyond …

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Introduction

There are 2.5 billion workers around the world who have no access to health and safety professionals. Control Banding (CB) strategies, which can help prevent work-related illness and injury for those without professional support, have grown rapidly during the last 20 years. There are now CB tools for all types of hazardous chemicals, including new emerging risks like nanomaterials, and for ergonomic hazards and injury prevention. Originally CB was conceived as an action-oriented *qualitative* risk assessment strategy, offering solutions and suggested control measures to users through "toolkits". But during the last decade CB has gone beyond its traditional qualitative approach with some chemical CB tools, such as Stoffenmanager® and EMKG-Expo-Tool, providing *quantitative* exposure assessments. Other quantitative chemical exposure assessments tools like ART, ECETOC TRA and MEASE also became available. Furthermore, user needs became more demanding and looked for tools that not only focused on CB, but additionally provided a complete chemicals management platform.

To be accepted by regulatory authorities and other stakeholders, including the occupational hygiene community, the coherence of the underlying exposure models and robust calibration with high quality exposure data has become increasingly important. At the 7th CB Workshop the results of the ETEAM study on the validation of lower tier exposure tools used for REACH were presented. Since then several new studies, also on higher tier exposure tools, have been published or are underway. There is increasing pressure on substitution of carcinogens, mutagens and reprotoxic (CMRs) chemicals, and the validation of different hazard or occupational exposure banding schemes have been further questioned as a consequence.

Finally, it has been shown that just "offering" a CB tool, without providing active support, does not automatically result in its use or its 'proper' use by SMEs. For successful implementation of CB and beyond…. strategies, aspects other than technical model reliability issues need to be covered.

The 8th International Control Banding Workshop discussed the complete picture of success and failure factors of CB and beyond… strategies.

Session 1 History, Implementation and Future of Control Banding

The meeting was opened by Andrea Hiddinga, President of IOHA. She welcomed over 40 delegates in the meeting room in Washington DC, and a further 30 following proceedings online.

The opening keynote lecture was given by John Cherrie. He provided some background on the origins of CB in the 1990s as a way for the regulator in Britain to provide simple advice to SMEs, who it was clear had little understanding of their legal obligations and generally had no access to expert advice. This initiative resulted in the COSHH-Essentials tool (http://coshh-essentials.org.uk). The diversity of models used by CB developers was identified as a barrier to improving tool reliability, limiting the

sharing of knowledge and data that could be used for calibration. He highlighted the need for research to validate tools, both in terms of accuracy and reliability, and to verify the effectiveness of CB tools in real workplaces. Four areas were suggested for developers to focus:

- Integration of training and support into the tool package;
- Seek to improve accuracy of estimated exposure by combining model estimates with measurements, for example using a Bayesian statistical framework as has been pioneered in the ART;
- Work to have “many tools” but a single exposure model;
- Find ways to ”nudge” users towards lower exposures by suggesting how they could modify their work processes not just adopt a higher band.

Wouter Fransman, from TNO in the Netherlands, spoke about the accuracy and reliability of exposure models. He identified that CB tool performance varies between process activities and scenario conditions, and that the results obtained with the tools may be affected by factors such as the professional experience and judgment of the tool user and level of available information. It is important that all tool users receive comprehensive training in tool use and that comprehensive guidance to tools is provided. However, models cannot and should not replace the collection of good quality exposure measurements. Ongoing development, adjustment, and recalibration of the tools with new measurement data are essential to ensure adequate characterization and control of worker exposure to hazardous substances. Dr Fransman finished with a vision of the future where CB tools could incorporate measurement data from real-time sensors and where information could be provided direct to workers via a cell phone app acting as a ‘personal job coach’.

The final talk in the first session, by Wes Chase from the Lawrence Livermore National Laboratory (LLNL), was about the quantitative validation of the CB Nanotool. This is one of the new tools that have been developed specifically to provide advice for organisations using or producing nanomaterials. The tool has an algorithm to determine a “severity” score, based on physical-chemical data such as surface chemistry, particle shape, particle diameter and solubility, along with information about the hazard, e.g. is the material carcinogenic or a reproductive toxin, plus an exposure “probability” based on the amount of material used, its dustiness/mistiness, the number of employees with similar exposure, along with the frequency and duration of operation. These scores are then used in a conventional control banding matrix to identify the appropriate degree of control. The tool was evaluated at LLNL using a variety of quantitative measurement methods including filter-based sampling, particle counting, and particle size distribution analysis. These quantitative analyses were able to validate the tool’s qualitative risk level outcomes in all 30 of the operations that were assessed. Dr Chase proposed that this control banding tool and approach can be relied upon in the absence of OELs or toxicological data. The CB Nanotool is now a required element of the LLNL Nanotechnology Safety Program.

Session 2 Evaluation of REACH tier I and 1.5 tools – the ETEAM study: follow up by tool owners

At the previous CB conference the results of the ETEAM project (*Evaluation of Tier 1 Exposure Assessment Models used under REACH)* on operational analysis and uncertainty, between user variability and external validation were presented. Clear advice was given to tool owners for further improvement of their tools. In this session Emily Lee (NIOSH) introduced the ETEAM project covering REACH tier 1 and 1.5 tools: ECETOC TRA v.2/v.3, EMKG-EXPO-TOOL 2.0, MEASE v.1.02.01 and

Stoffenmanager® 4.5. She then presented an overview of additional external validation studies carried out after the ETEAM project. Thereafter the floor was opened to the tool owners to provide an update about improvements / additional functionalities they had implemented in their tool.

Martin Tischer (BAuA) previewed the new EMKG-EXPO-TOOL software (beta version downloadable at https://www.baua.de/EN/Topics/Work-design/Hazardous-substances/REACH-assessment-unit/EMKG-Expo-Tool.html). He also presented a validation study of control guidance sheets for IBC filling and emptying, and drum filling with organic liquids. The underlying model is based on the UK COSHH-Essentials framework. The guidance has been shown to be protective. However, when BAuA investigated specific workplaces, deficits were seen in control measures, for example incorrect positioning of the local extract ventilation hoods or air velocity too low to capture all the pollutants, and this resulted in non-compliance. To raise awareness about proper design and use of these control measures BAuA now also provides videos and a manual for good working practice.

Henri Heussen (Cosanta) presented the improvements in Stoffenmanager® (www.stoffenmanager.com). Underpinned with ~6300 measurements (ETEAM and later external validation studies) he concluded that Stoffenmanager® is a balanced, robust and sufficiently conservative tool. With one exception for exposure to low volatile substances, released from spraying activities (aerosol formation - PROC7 and PROC11; 'Handling of liquids at high pressure resulting in substantial generation of mist or spray/haze'. For this scenario he recommended to use the 95th-percentile exposure estimation (instead of the 90th-percentile) or to comply with a Risk Characterization Ratio of 0.5 (instead of 1). This is clearly marked in the applicability domain of the tool. To reduce the between user variability Cosanta provides additional support such as training (including train the trainer), consultancy, webinars, instruction movies, a manual, and peer-reviewed user sessions.

The last speaker in this session, Daniel Vetter (ERBC), explained how MEASE 1 can be used for exposure assessment for metals and inorganic substances. The tool is based on a combined approach of ECETOC TRA, EASE and the health risk assessment guidance for metals (HERAG): the tool is downloadable at https://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php. In the development of MEASE 2, a refinement of the underlying initial exposure estimates will be made (external validation), additional risk management measures (RMMs) will be incorporated, a PROC selection guide will be added to reduce between user variability and a report generator will be included. Furthermore, an interface with Chesar (the ECHA CSA tool) will be implemented in the tool.

Session 3 Hazard banding / Occupational Exposure Banding

Different terms for the same phenomenon are used in the EU, US and other parts of the world. In addition, different hazard banding engines are used to derive the bands from the H-phrases, e.g. by NIOSH, COSHH and Stoffenmanager®. In some cases industry has also developed their own hazard banding schemes. Different hazard band approaches were presented in this session, including research comparing the pro's and con's of different schemes.

Theo Scheffers (TSAC) reported on a plea for the alignment and improvement of Hazard Banding / Occupational Exposure Banding (HB/OEB). He first gave an overview of the wealth of 'chemicals in the workplace control tools', pointing out the differences in OELVs, health hazard classifications,

hazard banding engines, exposure models, compliance statistics, handling mixtures and strategies/ policies. He identified more than 40 different hazard / occupational exposure banding engines, mostly based on expert driven allocation of H-phrases. Ir. Scheffers presented a scientific strength score method to different stakeholders in order to compare and align the different HB/OEB engines, although the owners of the engines did not show a great or no interest at all to start working on it.

Dorothea Koppisch (IFA) presented a hazard banding scheme as a non-OEL surrogate based on GHS. This scheme has been peer reviewed, published and implemented in Stoffenmanager® 7.0, replacing the original COSHH-Essentials hazard bands. It is a tiered assessment designed to promote substitution of hazardous substances with materials with less hazardous properties. Giving several worked examples she explained the rationale behind the approach: it is based on using the safety data sheet (SDS) as the primary source of information, it is exposure route specific and includes eye damage, inhalation, local skin damage and percutaneous absorption and takes account of dilution of the product during handling.

Finally, Thomas J. Lentz (NIOSH) presented an overview of the NIOSH OEB Process. It is intended for public health agencies, practicing occupational health and safety professionals serving SMEs, employers, trade associations, and labor organizations seeking risk management solutions for chemicals lacking occupational exposure limits. The guidance and strategy are described in a draft NIOSH guidance document and an online e-Tool has also been developed. Both are free and available online, and are being revised for release as final versions. The OEB provides a series of concrete steps to guide users through the evaluation of health hazard information and identification of the appropriate occupational exposure band from among five categories based on severity of health outcomes (bands A to E; band A is highest air concentrations, and band E is lowest air concentrations).

Session 4 Evaluation of quantitative exposure models

The ETEAM study has triggered more research groups to evaluate quantitative exposure models, mostly the Advanced REACH Tool (ART), ECETOC TRA and Stoffenmanager®. In this session the latest results of these studies were presented.

Emily Lee, from NIOSH, returned to speak about external validation of higher tier exposure assessment tools used under REACH. These data showed that the ART underestimated exposure levels for liquids with vapour pressure > 10Pa while for the same situations Stoffenmanager® 7 appeared to perform more consistently with an appropriate level of conservatism. The ECETOC TRAv3 appeared to lack conservatism.

Shao-Zu Huang, from the National Taiwan University in Taiwan, reported on an evaluation on the use of Stoffenmanager® 7 in Taiwan. Measurement data on solvents and exposure situations were collected from past exposure reports from the Taiwanese ILOSH. It was shown that there was a tendency to overestimate in low concentration scenarios and to underestimate in high concentration scenarios. When using the default 90-percentile Stoffenmanager® overestimated all situations demonstrating an appropriate level of conservatism. Incorporating Bayesian statistics resulted in more precise estimates.

Hanna Landberg, Lund University, provided a case-study evaluation of the risk assessment approach of the REACH legislation using exposure models (ART 1.5, ECETOC TRA 3.1 and Stoffenmanager® 6.1), and calculated risk characterization ratios of 239 scenarios using 45 e-SDS documents. The data put in question the generic ES recommended under the REACH legislation and she concluded that downstream users may get better estimates by assessing their own ES, especially for chemicals with low DNELS and high vapour pressure. To decrease the number of falsely identified safe scenarios she suggested assessors should use Stoffenmanager® as a Tier 1 model instead of the ECETOC TRA.

Plenary discussion: harmonization of models and hazard banding schemes?

After the last session a lively discussion started on harmonization of models and hazard banding schemes. Although from a professional point of view no one could reasonably be against harmonization, several hurdles were identified: for tool owners there was some reluctance for revisions because of the investment they had already made in their tool and a "not-invented by me" attitude, continuing acceptance by authorities and implementation costs for companies to adapt to a new scheme. In the EU, where model development is mainly driven by ECHA and the REACH Regulations, tool owners participate in a dialogue to describe the differences between the tools. More specifically, they work on mapping the different input parameters where possible. The meeting considered this can be seen as a first step towards harmonization. It was furthermore discussed if IOHA should take an active role in harmonization, and most were in favour of some sort of involvement. As an outcome from the Workshop it was recommended that the IOHA European members should make contact with ECHA asking to join the above mentioned working group.

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