POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Translation Inconsistencies in Published EHS Regulations Worldwide

Doug Strock
GLTaC, Midland, MI 48640

This poster will present examples of the various ways EHS regulations contain inconsistencies when translated into different languages around the world. While not meant to cite every inconsistency, the poster will highlight five instances where an SDS author may select an incorrect translation or struggle to identify which translation of a phrase is "compliant" when creating an SDS or label. With the stringent level of scrutiny applied to hazardous material shipments worldwide, the risk of a delayed shipment due to an improper translation pulled directly from a published regulation does exist. Two experts reviewing the same document but viewing different references may also disagree on whether or not the document is "compliant". The poster will shine some light on the scope of this issue and raise awareness among SDS authors. When performing checks against global EHS regulations, we encounter these review questions regularly from our clients. This poster was independently reviewed for accuracy and correct regulatory reference citations by a regulatory research service.

SDS and Label Author Registry: Important Update

Denese A. Deeds, CIH, FAIHA and Chandra D. Gioiello, MS, CIH
For AIHA Registries LLC

Some important changes are being made to the AIHA/SCHC SDS and Label Author Registry Program that affect both registered authors and those seeking registration. An alternative to re-testing will be offered at the end of the registration cycle. A new designation for registrants is available (more letters after your signature!). Our poster will present these changes, the new Body of Knowledge and the new on-line test.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Assess the Impact of Environmental Counseling on Pregnant Women's Perception and Behavior about Environmental Hazards

Student: Sewit Tedla
Co-Authors: Kali Frost, Richard M. Fairbanks School of Public Health; Aaron Vaillancourt, Indiana University School of Medicine; and David Hass, Indiana University School of Medicine
Faculty Advisor: Shahid Parvez, Ph.D.
Institution: Richard M. Fairbanks School of Public Health at Indiana University - Purdue University Indianapolis

Increase use of synthetic chemicals elevates the risk of preconception and prenatal exposure which negatively affect fetal development and lead to chronic health outcomes. In this project we are studying a cohort of pregnant women to understand their perception and behavior about chemicals present in food, drinking water, ambient and occupational environment, and whether environmental counseling can be effective in changing their perception or behavior to minimize the exposure. We designed the counseling materials to educate pregnant women about common exposure pathways and methods to minimize exposure. We also designed pre and post counseling surveys to evaluate the effectiveness of counseling on pregnant women's' perception and behavior. The pregnant women consented and recruited at the time of prenatal visit at the Eskenazi Health Center, West 38th Street Indianapolis. Each participant completed a pre-counseling survey, followed by counseling. The post-counseling survey is performed on their next scheduled visit, typically after 4 weeks. Currently, the enrollment of pregnant women and counseling are in-progress and tentatively will be completed by April 2016. Analysis of the surveys will be performed after we meet our recruitment goal. This study will help to determine whether environmental counseling can be effective in minimizing maternal exposure. The data from this research will help public health professionals, clinicians, and reproductive health professionals assess the benefits of incorporating environmental counseling into prenatal care.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Advancing Hazard Communication for Chemical Accident Prevention: Review of Risk Management Plans for Chemical Safety Improvements

Student: Hayley Byra
Faculty Advisor: Joel Tickner, Sc.D.
Institution: University of Massachusetts Lowell

Toxic and hazardous chemicals are stored, transported, and manufactured in large quantities throughout the United States for a number of industrial processes. Preventing chemical spills and accidental or terrorism-related releases of hazardous chemicals is a major concern regarding the health and safety of many communities, workers, and the environment. Risk reduction – or chemical site security is also a concern in the post-9/11 world. Upon release certain chemicals have the ability to create poisonous gas clouds that could potentially travel miles, and injure or kill thousands in the process.

Facilities that use extremely hazardous chemicals are required to comply with Environmental Protection Agency's (EPA) Risk Management Plan (RMP) program; - however the RMP process does not indicate if a facility has chosen to transition to safer a chemical when companies delist from the program. The goal of this research is to examine the development of sustainable and safer industry practices for the 101 facilities that have the largest worst case scenarios, potential impacts affecting more than one million people, and identify facilities that have successfully adopted less acutely hazardous chemicals or processes.

The facilities that were involved have recently deregistered from the RMP in the last five years, for reasons other than terminating operations or switching ownership. We conducted a survey that was distributed to one hundred high risk facilities that stored the largest amounts of hazardous chemicals, or occupied multiple locations. Analysis of these surveys will be performed when the desired quota is returned. Converting to a safer substance or method of operation eliminates the ever-present risk of an unintended accident and in many cases the need for guards, gates, and other forms of high security measures.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Technical and Logistical Challenges in Implementing The Globally (Un)Harmonized System (GHS) of Classification and Labelling of Chemicals

Ari S. Lewis, M.S.; Jiaru Zhang, M.P.H.; Daniella M. Pizzurro, Ph.D.
Gradient, Cambridge, MA 02138

In 2003, the United Nations (UN) published the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a set of "harmonized criteria" for identifying chemical hazards and requirements for labeling and safety data sheets (SDSs). To date, 72 countries have incorporated or are in the process of incorporating GHS into their regulatory frameworks. Because of its widespread implementation, identifying hazards accurately and consistently is becoming increasingly important for regulators and companies at all points in the supply chain. Although one of the GHS's primary objectives is to "harmonize" hazard communication, it has been inconsistently adopted, often resulting in different hazard classifications for one chemical or product. Key factors that can lead to such divergent classifications include reliance on supplier information of variable quality, consideration of country-specific classifications and requirements, differential access to data and information sources, and use of read-across substances to determine the toxicity of data-poor compounds. Moreover, several elements of the GHS rely on professional judgment, requiring toxicology and chemistry expertise to reach weight-of-evidence conclusions. Differences in hazard assignments for the same chemical can cause confusion throughout the supply chain and may invite the scrutiny of competitors, downstream suppliers, and regulators. Developing a successful strategy for conducting and documenting scientifically sound hazard assessments can promote worker safety, meet mandatory regulatory requirements (such as those outlined in the 2016 Occupational Safety and Health Administration Hazard Communication [OSHA HazCom] guidance), optimize the protection of confidential business information (CBI), and serve as the foundation of a proactive product stewardship program.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

An Iterative and Multidisciplinary Framework for Determining Read-Across for Hazard Assessment

Daniella M. Pizzurro, Ph.D.; Jiaru Zhang, M.P.H.; Jim W. Rice, Ph.D.; Ari S. Lewis, M.S.
Gradient, Cambridge, MA 02138

For global chemical compliance and safety data sheet (SDS) generation, we analyzed toxicological data for a comprehensive portfolio of chemicals. Many of these substances have no readily available toxicity data, necessitating "read-across" or "surrogate" identification. To facilitate adherence to a consistent and scientifically sound approach, we developed an iterative, multidisciplinary framework for identifying high-quality read-across chemicals that can inform the toxicological assessment of a data-poor chemical of interest (COI). Our read-across identification and evaluation approach involves consistently preserving COI reactive functional groups, considering structural alerts and bioavailability, and using an internally developed database of chemical groupings to validate or challenge potential hazard profiles. Mechanistic and metabolic data are incorporated when possible and necessary. We have reviewed over 700 COIs to date using our read-across framework and observed (1) chemical expertise and rationale documentation are particularly important for complex chemicals (*e.g.*, of unknown or variable composition, complex reaction products, and biological materials [UVCBs]), (2) systematic use of chemical groupings and structure-activity relationships streamlines read-across selection and ensures consistency within a large portfolio of chemicals, and (3) regular communication and collaboration between toxicologists and chemists is essential for successful application of the framework. Lastly, the framework includes quality assurance protocols and requires that users compare toxicity data for multiple surrogates to ensure concordance. Appropriate application of the read-across approach ultimately lowers analytical costs and dependence on animal testing, fosters safer chemical use, and increases compliance with hazard communication frameworks such as the Globally Harmonized System for Classification and Labelling of Chemicals (GHS).

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Understanding WoE under New OSHA Guidance: Endpoint-by-endpoint Considerations for Rigorous GHS-based Hazard Evaluations

Jiaru Zhang, M.P.H.; Daniella M. Pizzurro, Ph.D.; Ari S. Lewis, M.S.
Gradient, Cambridge, MA 02138

The Globally Harmonized System of Classification and Labelling Chemicals (GHS) is a hazard identification (classification) and communication (labeling) framework being implemented around the world. It serves as a building block for hazard communication regulations, such as the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS). Despite GHS's widespread adoption, there are many gray areas in its interpretation that could lead to conflicting hazard conclusions. Recognizing these gray areas, in early 2016, OSHA released two guidance documents to improve the quality and consistency of the hazard classification process and associated information provided on safety data sheets (SDS), labels, and in trainings. Drawing from OSHA's Guidance on Data Evaluation for Weight of Evidence (WoE) Determination and our experience with over 1,600 chemical evaluations, we present our approach for scientifically defensible hazard assessment. This poster highlights key pitfalls and considerations, use of read-across substances as well as the need for high-quality and multiple data sources, independent evaluation of study or dossier conclusions, and consideration of important physicochemical (*e.g.*, solubility) or toxicological (*e.g.*, corrosivity) properties. In addition, we discuss evaluation approaches for health endpoints that can lead to variable hazard conclusions, including identification of adverse effects for classifying single target organ toxicity (STOT) following repeated exposure, role of mode of action (MoA) in carcinogenicity evaluation, maternal toxicity's role in reproductive and developmental outcomes, role of solubility in aquatic toxicity evaluations, *etc*. Careful consideration and documentation of these issues is critical to developing a consistent and rigorous approach to hazard classification.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Preparing for the 2016 Chemical Data Reporting Rule

Dan Wiant, MPH; Joanne Houck; Michael Derelanko, PhD; Elizabeth Dederick, PhD
Critical Path Services, a knoell company
Garnet Valley, PA 19060

The Chemical Data Reporting Rule (CDR) requires manufacturers and importers to provide information on production and processing and use for certain chemicals in commerce. Submission of the CDR is required every four years, and the next submission period is June 1 through September 30, 2016. Chemicals are triggered for reporting if they were manufactured or imported at 25,000 pounds/site during any year 2012 - 2015. For chemical substances subject to specific TSCA actions, the reporting threshold is reduced to 2,500 pounds/site. These specific TSCA actions include Section 4 rules, Enforceable Consent Agreements, Section 5(a)(2) SNURS, Section 5(b)(4) rules, Section 5(e) orders, Section 5(f) orders, Section 5 or 7 civil actions, and Section 6 rules. The TSCA action status of each chemical substance is determined as of June 1, 2016. For each chemical substance subject to reporting, production volume must be provided for 2012, 2013 and 2014. For 2015, the principal reporting year, processing and use information must also be reported. There are several exemptions from reporting: naturally occurring chemical substances, certain polymers, microorganisms and specific forms of natural gas and water. Partial exemptions exist for listed petroleum process streams, and “low current interest” chemicals. Exemptions also exist for small businesses. This poster will review the process for identifying reportable chemicals, and the collection and submission of the required data during the 2016 CDR reporting round.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

How to Author a Combined SDS and Label Compliant with OSHA HazCom 2012 and WHMIS 2015

Jeremy Long; Adele Thornton; Joanne Houck; Elizabeth Dederick, PhD
Critical Path Services, a knoell company
Garnet Valley, PA 19060

The alignment of Canada's WHMIS (Workplace Hazardous Materials Information System) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has made it possible for suppliers to generate a single safety data sheet (SDS) and label for a product that meets both US HazCom 2012 and Canadian WHMIS 2015 requirements. The ability to generate a single SDS and label for a product not only simplifies trade between the US and Canada, but also streamlines and improves the communication of information to employees working with these chemicals. However, when authoring a single combined US and Canadian SDS or label, it is important to include all of the required information from both jurisdictions such as country-specific occupational exposure limits (OELs) and chemical inventory listings. Even though the WHMIS 2015 and HazCom 2012 regulations are both aligned with GHS, there are some notable variations that must be implemented in a combined SDS or label in order to be compliant in both jurisdictions. For example, WHMIS 2015 has additional hazard classes that must be incorporated into a combined label or SDS even though they are unique to Canada. The objective of this poster is to describe the process for authoring a combined SDS and label that is compliant with both OSHA HazCom 2012 and WHMIS 2015.

(Q)SAR in Regulatory Praxis – Experience of a Service Provider

A. Szymoszek, A. Gerloff-Elias
Dr. Knoell Consult, Dynamostr. 19, 68165 Mannheim, Germany

According to REACH Annex XI, 1.3, "Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property". These results can be used instead of testing if certain relevant conditions are met [1].

In the regulatory praxis of our company, submitting dossiers of a large number of chemicals in REACH Phase I and II, (Q)SAR techniques were often used and incorporated in registration strategies. In particular, results obtained from (Q)SAR models were submitted and accepted as key values, supporting information, or contributions to the weight of evidence approach. The endpoints addressed included mainly physico-chemical and environmental fate related properties and furthermore to less extent ecotoxicological and human toxicity information.

We present a summary of (Q)SAR use by our company throughout the REACH registration Phases I and II. The statistics covers the purpose of (Q)SAR studies (key study, supporting study, weight of evidence), substance types (mono-constituent, multi-constituent, UVCB), endpoints where (Q)SARs were applied, as well as models and software used and other related information. In the outlook, our (Q)SAR related plans and needs concerning the Phase III of REACH will be addressed.

Reference:

[1]REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Recent global regulatory developments and data requirements for endocrine disruptor testing and assessment

Dr Martina Duft, Dr Agnes Schimera, Dr Anja Rämisch,
Dr Knoell Consult GmbH, Dynamostr 19, D-68165 Mannheim, Germany

Keywords: Endocrine disrupting chemicals, global registration, data requirements

Abstract:

Despite decades of scientific research and extensive discussions and work within regulatory panels, an intended consensus on the assessment of substances with an endocrine disrupting potential, so-called endocrine disruptors, has not yet been reached.

Several diverging proposals for an assessment of plant protections products or biocidal products to consider potential endocrine effects are available within the European Union, e.g. by Denmark, UK/Germany or France. Under REACh, substances with endocrine disrupting potential can be considered as substances of very high concern and may be subject to authorization. Whereas European proposals are mostly aiming at a hazard-based assessment proposing endocrine disrupting properties as cut-off criterion with few exceptions, US EPA follows a different approach and pursues a comprehensive two-tiered screening program still to be followed by risk-based assessment. In other areas of the world, e.g. Canada, Brazil, China, Japan or Korea, national programs for the assessment of endocrine disrupting chemicals have been launched or are about to follow other proposals. As scientific criteria for the evaluation of endocrine disrupting properties of a substance are still not yet available, assessment is mostly conducted on a case-by-case basis at the moment.

For companies intending or supporting global registrations for their substances, this results in substantial uncertainty regarding data requirements or testing and assessment strategies. This presentation aims to give a global overview on present regulatory proposals, recent regulatory developments and data requirements for the assessment of endocrine disrupting chemicals.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Effective Use of Color Inkjet Print Technology for the Creation of GHS Labels

Todd Campbell
Brandywine Drum Labels, LLC
Paoli, PA 19301

With GHS reliance on color pictograms as a primary means to communicate workplace hazards, pigment based color inkjet technology provides a cost-effective option in the search for an efficient and effective method of producing HCS 2012 compliant hazard communication labels.

The challenge facing any organization with respect to systems that utilize in-house printing technologies is ensuring that labels created using these methods meet all aspects of global regulations. Absent a single comprehensive set of test criteria, regulatory compliance professionals are challenged with reviewing a variety of standards in their efforts to ensure compliance with existing standards and regulations. The testing protocol outlined here follows this same approach. By referencing the applicable sections included in the BS5609 Maritime standard, 49 CFR, 29 CFR, EC 1272 and the ACA HMIS UV Resistance Standard the research endeavored to gain the conclusive proof necessary to confirm that pigment based color inkjet generated labels could meet all of these requirements.

The data indicates that the most critical steps in the process involved choosing the correct type of inkjet printing device and pairing it with a certified GHS compliant label face stock. With proper due diligence, regulatory compliance professionals can be confident their company's labels meet all existing and proposed standards for the labeling of chemical products when using pigment based color inkjet generated GHS labels.

Pressure Sensitive GHS Labels, BS 5609 and IMDG Compliance

Bill Sargent
Reliance Label Solutions, Paola, KS 66071

As the industry has transitioned into the world of HazCom 2012 and GHS, there are many challenges, confusion and mis-conceptions in the area of bulk container label printing. There are clear misunderstandings as to what IMDG and BS 5609 compliance truly means and what kind of exposure companies have when they do not meet those standards.

GHS container labels that are shipped over the international waterways must meet the International Maritime Dangerous Goods (IMDG) requirements. Although the IMDG regulation does **not** require a label to be BS 5609 certified, the BS 5609 designation is recognized as the only certification.

The BS 5609 certification was developed as a method of testing the printed label durability under conditions that would emulate the label being submerged in saltwater and abrasive sand for 90 days. The label must remain affixed to the container with the printed image (including the red frame, pictograms and precautionary text) remaining identifiable and readable.

The BS 5609 certification is a two-part certification for both the label material and the printed information on the label. Both elements must be tested successfully, as evidenced by separate certifications, for a label to achieve the full BS 5609 certification. Many companies contract with independent testing laboratories to test their labels for BS 5609 compliance. While any label or printer supplier can carry out their own internal tests for IMDG compliance, the BS 5609 certification requires that the testing be carried out by a certified independent testing laboratory.

POSTER ABSTRACTS
Spring 2016
Ft. Lauderdale, Florida

Lean and EHS (and GHS)

Kathy Malone
Manguard Systems, Inc.
Fenton, MI 48430

Lean is a topic that is tangentially or directly impacting many Environmental, Health and Safety (EHS) professionals.

If it hasn't impacted you yet, it might soon. Lean may provide a means to achieve the ever more frequently requested "do more with less".

This poster will:

- Show the main "framework" of Lean as developed in the Toyota Production System (TPS)

- Demonstrate key elements of this framework as they relate to EHS, and specifically GHS

- Show metrics for an example of where cross enterprise Lean can achieve more dramatic productivity improvements than internal Lean