


Legal Aspects of the Practical Implementation of the GHS in the US – a/k/a HCS 2012

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Lawrence P. Halprin

Lawrence Halprin is a partner in Keller and Heckman's workplace safety and health, chemical regulation and litigation practice groups. He is nationally recognized for his work in these areas. He represented numerous parties in the OSHA GHS Rulemaking and the American Petroleum Institute (API) in challenging certain aspects of the GHS Amendment to the OSHA HazCom Standard. That litigation was settled in February 2014 and will be a focus of this workshop.

Mr. Halprin's workplace safety and health practice includes representing clients in: OSHA and MSHA enforcement actions and citation contests; compliance counseling and training; incident investigations, compliance audits and program reviews; federal (OSHA, MSHA and NIOSH) and state rulemakings and stakeholder processes; pre-enforcement challenges to final agency rules; legislative reform and oversight initiatives; and the development of national consensus standards through the ANSI, NFPA and ASTM processes, and TLVs under the ACGIH process.

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Mr. Halprin's engineering and financial background and extensive knowledge of OSHA rulemakings have greatly enhanced his ability to: provide compliance counseling and represent clients in enforcement actions; and evaluate and critique rulemaking proposals and suggest alternative approaches. On behalf of one or more clients, Mr. Halprin has participated in almost every major OSHA rulemaking over the past 25 years as well as numerous Cal-OSHA rulemakings.

Topics to be Covered

- Development of HCS 2012
- Creating new concerns and highlighting pre-existing concerns
- Legal Challenges to HCS 2012
- Future Enforcement of the HCS

Development of HCS 2012

- Background
  - HCS adopted in 1984; numerous revisions
  - Performance-based, ambiguous
  - Didn't facilitate uniformity or harmonization
  - Enormous Change in Approach under the GHS
  - Not simply a matter of taking existing info from old SDS form or label and inserting it into new form

Development of HCS 2012

- **Background**

HCS 1994	HCS 2012
Hazard Determination	Hazard Classification
Single positive study rule	Weight of evidence
Based on association, not causation	Based on causation
0.1% cancer threshold	Multiple 0.1 % thresholds
	Synergistic effects, and structure activity relationships
NTP & IARC presumptions	No NTP or IARC presumption.
Clip SDS for ingredients together	Integrated SDS

Development of HCS 2012

- **Background**

HCS 1994	HCS 2012
Mixture: "Mixture" means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.	***Mixture* means a combination or a solution composed of two or more substances in which they do not react.**
Complex mixture not defined	**Complex mixture not defined**

No substantive change per preamble to final rule

Development of HCS 2012

- **Background**

HCS 1994	HCS 2012
Substance: undefined.	***Substance*** **means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.**

- No guidance in HCS 2012 on how to take impurities into account in classifying the substance.

Health Hazard Classification

- Substance v. Mixture
  - **Substance**
    - **Weight of evidence (WOE) analysis of available data**
  - **Mixture (hierarchy of approaches)**
    - **WOE to adequate test data on mixture**
    - **WOE to adequate data on ingredients and substantially similar mixture**
    - **Bridging principles**
    - **Threshold cutoff levels for each hazard**

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Development of HCS 2012

- **Characterization of Petroleum Streams (UVCBs)**
  - **OSHA and petroleum industry disagreed as to whether the 750 +/- types of petroleum streams are substances or mixtures.**
    - **If substances**
    - **If mixtures**
  - **Imagine how different the tasks of chemical classification and SDS and label development become if the chemical is treated as a (complex) mixture rather than a substance.**
  - **Same issue is probably presented by virtually all of the other 11,000 UVCBs found in nature, and the chemicals extracted or distilled from those feed streams – colors, flavors, coal, etc.**
  - **No other industry chose to formally address the issue with OSHA. Some will try to piggy back.**

Development of HCS 2012

- **Hazards Not Otherwise Classified**
  - **HCS 1994 specified 10 physical hazards categories, no vague HNOCs catch-all category, anything else was covered by General Duty Clause**
  - **HCS 1994 specified a non-exclusive group of 11 health hazards, effectively including health HNOCs, but no more were being identified by OSHA**
  - **Suddenly, there were two new, undefined and potentially limitless hazard categories that were likely to be identified by OSHA after the fact**

Development of HCS 2012

- **Combustible Dust**
  - **Does the HCS obligate the manufacturer to recognize the hazards posed by known or anticipated downstream uses of the chemical?**
    - **At what point is that product a hazardous chemical?**
    - **How may the language on the SDS and/or label be modified to avoid overstating the hazard posed by the product.?**
  - **Does HCS 1994 cover CD?**
    - **Our understanding: OSHA did not intend to cover CD under HCS when HCS was first adopted.**
    - **Two physical hazard categories were potentially applicable to CD**
      - **Flammable solid**
      - **Explosive: adjective or noun?**
    - **Preamble to HCS 2012 rule indicates that "explosive" was used in HCS 1994 as a noun.**

Development of HCS 2012

- **Issues Raised by the One-Time Label Rule**
  - Equally applicable to HCS 1994 and HCS 2012
  - Scope: for solid items that are processed downstream, release hazardous chemicals, and therefore are not articles.
  - (f)(5): Except for alternative labeling of stationary process vessels and temporary use containers, the employer must ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with the required information:
    - No exception for one-time label rule
    - Needed a fix
      - Customer obligation? When is it triggered?
      - Non-stationary process vessel

Development of HCS 2012

- **Background**
  - ANPRM 2007
  - NPRM 2009
  - Rule adopted in 2012, being phased in through 2015
  - Legal challenges filed in June 2012 and API settled in February 2014
  - Parties talking past each other in rulemaking and Geneva meetings
  - Needed to be addressed during period after ANPRM was issued

Development of HCS 2012

- **Background**
  - Facilitates significant harmonization
  - Concerns
    - Effectiveness? Costs dramatically underestimated
    - Impractical compliance deadlines (e.g., cascading deluges of new info)
    - Confusing requirements
    - Heavy dose of the precautionary principle
    - Inconsistent with EU CLP on significant issues
    - Inconsistent with proposed Canadian Hazardous Product Regulations on significant issues

Petitions for Review

- API
  - Petroleum streams
    - Substance v. Mixture
    - Naming of chemical
    - Listing of groups/individual ingredients on SDS
    - Use of risk assessment
  - Combustible dust and 1-time label rule
    - Limit scope and qualify labeling so not misleading
    - Accept responsibility for addressing hazards of known downstream uses
  - HNOCs
    - No definition or limitation on scope as written
  - STOT Classification – not as flexible as EU CLP

Petitions for Review

- ACC
  - Combustible dust: definition and scope
- National Oil Seed Processors
  - Coverage of combustible dust
- Amer. Tort Reform. Assn.
  - Preemption of state tort suits? HCS v. Tort
    - No obligation under HCS to test- composition or effects (physical or health)
    - No label updating requirement for 14 yrs
    - 90 days for SDS, 6 months for label, regardless of nature of new info
    - No apparent obligation to update literature search under HCS (as distinct from tort law)

Health Hazard Classification

- Substance v. Mixture for Complex Petroleum Chemicals (category of UVCBs)
  - Crude oil is created through **a complex series of chemical reactions**
  - Thousands of chemical structures
  - Petroleum industry has health hazard test data on petroleum streams not 1000's individual constituents
  - API: crude oil and all complex petroleum streams derived from crude oil are substances
  - OSHA: crude oil and chemicals extracted from crude oil without a chemical reaction are complex mixtures

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Health Hazard Classification

- Substance v. Mixture for Complex Petroleum Chemicals (category of UVCBs)
  - HCS 1994
    - "Mixture" means any combination of two or more chemicals if the combination **is not, in whole or in part, the result of a chemical reaction** [emphasis added].
    - Therefore, a “substance” would logically be any single chemical or any combination of chemicals that is, in whole or part, the result of a chemical reaction.

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Health Hazard Classification

- Substance v. Mixture for Complex Petroleum Chemicals (category of UVCBs)
  - **HCS 2012**
    - "**Mixture**" means a combination or a solution composed of two or more substances **in which they do not react**.
    - "**Substance**" means chemical elements and their compounds **in the natural state or obtained by any production process**, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
    - Different words, but, per OSHA, no change in meaning

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Health Hazard Classification

- Substance v. Mixture for Complex Petroleum Chemicals (category of UVCBs)
  - **API-OSHA Settlement**
    - **Hybrid approach to classification**
    - **Permits reliance on test data from the same and substantially similar chemicals**
    - **Defines what is meant by a substantially similar chemical for purposes of petroleum streams**
    - **Explains the nature of test data that may be relied upon to overcome the presumption that the threshold cutoff values govern streams containing CMRs (must support strong inference, need not be overwhelming evidence)**

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SDS "Ingredient" Disclosure

- Substance v. Mixture for Complex Petroleum Chemicals (category of UVCBs)
  - **API-OSHA Settlement**
    - **Where there is "reliable and good quality" data supporting a weight of evidence determination that a constituent in a petroleum stream poses no health risk (as per A.0.4.3.3) in a downstream use of the stream, it need not be disclosed on the SDS.**
    - **Notwithstanding Section 3 of Appendix D (SDS format) that requires the listing of hazardous ingredients above the threshold cutoff level.**

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Health Hazard Classification

- Substance v. Mixture Issues
  - **Unresolved issues**
    - **How to classify an OSHA-recognized "substance" containing preservatives or impurities where the manufacturer does not have data on the substance (as a whole)**
    - **Whether these principles are applicable to other UVCBs**
    - **The extent to which risk (rather than inherent hazard) is determinative**

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Hazard Classification

- Hazards Not Otherwise Classified
  - Challenged by API as open-ended
  - API-OSHA Settlement
    - **Material impairment of health or functional capacity**
    - **Health effect: based on weight of evidence, not just because a single positive test**
    - **Intrinsic chemical hazard, not one caused by added heat, slippery condition, etc.**

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Combustible Dust (CD)

- API challenged manner in which CD was covered, not whether it was covered
  - Acceptable SDS language
    - **This product is not hazardous in the form in which it is shipped by the manufacturer, but may become hazardous through downstream activities (e.g. grinding, pulverizing) that reduce its particle size. Those hazards are described below.**

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Combustible Dust (CD)

- API challenged manner in which CD was covered, not whether it was covered
  - SDS and Shipped Container Label Hazard Statement
    - ***If converted to small particles during further processing, handling, or by other means*, may form combustible dust concentrations in air.**
    - ***If small particles are generated during further processing, handling or by other means*, may form combustible dust concentrations in air.**

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Combustible Dust (CD)

- API challenged manner in which CD was covered, not whether it was covered
  - API-OSHA Settlement Clarified In-Plant Label Requirements Under One-time label Rule
    - **Shipped container**
    - **Stationary process vessel: alternative labeling**
    - **Non-stationary process vessel: label container**
    - **Processing before being placed in container**

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Effect Upon Various OSHA Standards and General Duty Clause

- Hazard Communication Standard (HCS)
- Laboratory Standard
- PELs and OELs
- Comprehensive substance-specific standards
- Chemical Emergency Response (HAZWOPER)
- Respirators
- Other PPE
- Flammable Liquids
- Process Safety Management
- Fire Brigades
- Welding, Cutting and Brazing
- Employee exposure and medical records
- General Duty Clause

Compliance:
List of hazardous chemicals

- Even with a complete set of SDSs, employers have been cited for:
  - An outdated list of chemicals
  - A list that identified a chemical with a different name than the one appearing on the SDS

LABELS: Updating of Labels

HCS-1994

- Manufacturers, importers, distributors and employer-users must revise labels within 3 months of becoming aware of any significant information regarding the hazards of a chemical
- A stay on enforcement of this provision had been in effect for approx. 15 years

HCS-2012

- Manufacturers, importers, distributors and employer-users must revise labels within 6 months of becoming aware of any significant information regarding the hazards of a chemicals
- Compliance with the HCS may not satisfy tort law on this point

Formulator or User Reliance on Supplier SDS or Label?

- 1910.1200(d) Hazard Classification
  - Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer ….
- 1910.1200(f)(6) Workplace Labeling
  - [T]he employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with either … the information specified under paragraphs (f)(1)(i) through (v) of this section for labels on shipped containers; or ….
- Suggests that reliance is limited to classification and does not extend to signal word, pictogram, hazard statement or precautionary statements

Compliance
TRAINING: When to train

- **When:**
  - Prior to initial assignment to job with potential exposure to haz chem in their work area (even if not part of assigned task)
  - When new chemical haz on which employee not previously trained is introduced
  - Training may cover categories of hazards (e.g. flammability, carcinogens)
  - Chemical-specific data must be available through labels and SDS

IMPLEMENTATION: Effective Date and Compliance Deadlines

- **EFFECTIVE DATE:** May 25, 2012 - Began official transition period. May comply with HCS-1994, HCS-2012 or both subject to the following deadlines.
- **COMPLIANCE DEADLINE 1:** December 1, 2013
  - New label and SDS formats and elements
- **COMPLIANCE DEADLINE 2:** June 1, 2015
  - Hazard classification, SDS, and shipped container labels. (Exception: until 12/1/2015, distributors may ship products that were labeled and shipped by manufacturers under the old system prior to 6/1/2015.)
- **COMPLIANCE DEADLINE 3:** June 1, 2016
  - Update alternative workplace labeling and hazard communication programs as necessary
  - Provide additional employee training for new information received as a result of the final rule (newly identified physical or health hazards)

IMPLEMENTATION: OSHA Enforcement of HCS-1994

- HCS
  - Missing or inadequate written program
  - Failure to provide training
  - Failure to maintain SDS or chemical inventory
  - The exact product in an SDS is no longer being ordered, but the SDS library has not been updated
    - Failure to label in-plant containers
    - Few cases of inadequate MSDS or label
- PPE
  - Failure to use recommended PPE

IMPLEMENTATION: OSHA Enforcement of HCS-2012

- OSHA has placed an increased emphasis on chemical safety
- OSHA views the current penalty structure as insufficient
- OSHA will likely continue to make HCS one of its most frequently cited standards
  - In fact, in 2012, the second-most frequent, behind fall protection, and 9th highest in penalties

Other Issues

- Complying with HCS 1994, HCS 2012 or both?
- Dual HCS 2012 and CPSC FHSA labeling?
- Individual ingredient below threshold cutoff level, but aggregate of ingredient class posing health hazard is above threshold cutoff level?
- Reliance on supplier's precautionary statements? (v. hazard classification)
- Conflicts with proposed Canadian system

Thank you

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