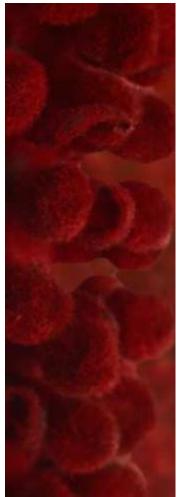
### Society for Chemical Hazard Communication Spring 2018 Meeting

Mexican GHS Update

April 24, 2018

Michael S. Wenk, M.S. The Acta Group Washington, D.C. www.actagroup.com





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Regulatory Consulting Firm

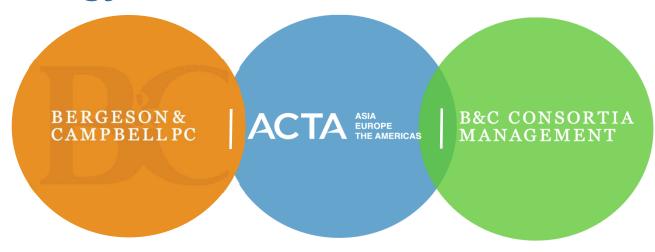
Law Firm

Consortia Management Firm

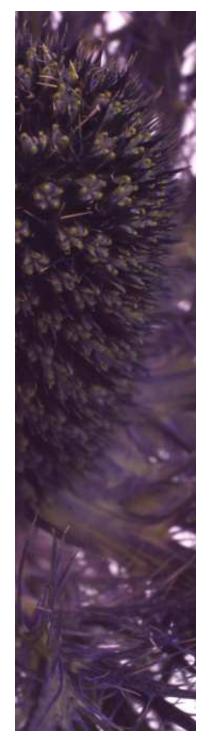


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## Three Related Firms, One Global Strategy



 Bergeson & Campbell, P.C., The Acta Group (Acta®), and B&C® Consortia Management, L.L.C. assist our clients in shepherding their chemical products and related services <u>from conception to</u> <u>distribution</u> and keeping them in the marketplace globally







#### **About Acta**

- A global scientific and regulatory consulting firm
- Strategic, comprehensive support
- Scientists, regulatory specialists, business strategists
- Experience in industry, research, and government
- Acta offices in Beijing, China; Manchester, UK; and Washington, DC











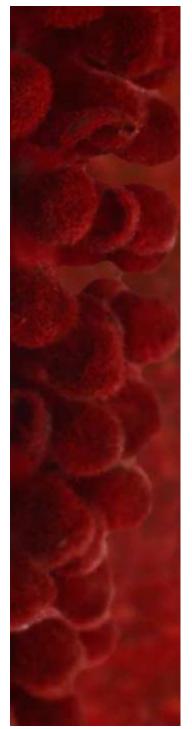
- Overview of Mexican Regulatory Structure (Terms and Format)
- Current Mexican Safety Data Sheet (SDS)
   Regulation
- Examination of United Nations (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Regulation
- Unique Aspects
- Relationship to U.S. GHS (Hazard Communication Standard (HCS) 2012) and Canadian Workplace Hazardous Materials Information System (WHMIS) 2015 Requirements
- Concluding Thoughts





### Overview of Mexican Regulatory Structure

- Competent authorities are "Ministries"
- Be careful: In many cases, multiple Ministries may have jurisdiction over a substance, based on intended use!
- Regulations published in the <u>Diario Oficial de</u> <u>la Federación</u> (Official Journal) -- similar to <u>Federal Register</u>

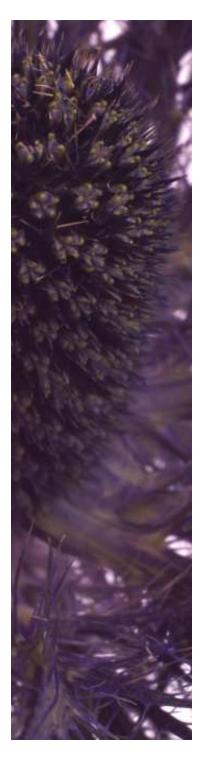


### **Mexican Regulatory Standards**

- Multiple types:
  - "NOM": Norma Oficial Mexicana (Official Mexican Standard)
    - NOMs prepared by Dirección General de Normas (DGN) (General Directorate of Standards)
    - Published in Diario Oficial de la Federación
    - Mandatory!



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### **Mexican Regulatory Standards**

- "NMX": Norma Mexicana
  - > NMXs prepared by national standardization bodies
  - Voluntary
  - HOWEVER: Can become mandatory when referred to under a NOM
- "PROY": Proyecto
  - Proposed draft standard
  - Not official until all updates and revisions are completed





### **Legislative Format in Mexico**

- Format is type of legislation (NOM or NMX) -- number of legislation in numerical order for that year -- issuing Ministry or authority -- year of issuance
- NOM-018-STPS-2015
- STPS is Secretaría del Trabajo y Previsión Social (Ministry of Labor and Social Security)



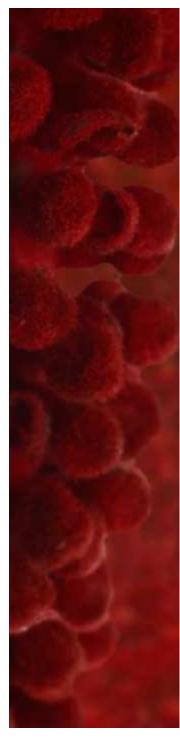
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### **Current Mexican SDS Regulation**

- 2011 -- First North American country to publish GHS guidelines
- Guidelines -- under NMX-R-019-SCFI-2011 -- were voluntary
- Did <u>not</u> make alignment mandatory with NOM-018-STPS-2000 (Mexico's other hazardous chemicals safety regulation)





#### **GHS in Mexico -- Overview**

- NOM-018-STPS-2015 -- "Sistema armonizado para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo"
  - "Harmonized System for the Identification and Communication of Hazards and Risks by Hazardous Chemical Substances in Work Centers"
- Implements the fifth revised edition of the UN Globally Harmonized System of Classification and Labelling of Chemicals (5th Rev. GHS), with all building blocks
- Consists of 16 sections, five Appendices, and two Guides
- Published October 9, 2015
- In force three years after publication -- October 8,
   2018





#### **GHS** in Mexico -- Overview

- Replaces NMX-019-SCFI-2011 -- Secretaria de Comercio y Fomento Industrial (Secretary of Commerce and Industrial Development)
- Competent authority is the Secretaría del Trabajo y Previsión Social (Ministry of Labor and Social Security, STPS)
- Regulates chemical substances and mixtures in workplace ONLY
- NOM-018-STPS-2015 does not provide any list of harmonized classifications or pre-classifications like the European Union (EU) Classification, Labelling and Packaging of Substances and Mixtures (CLP) or Canada Hazardous Products Regulations (HPR) have done





#### **GHS** in Mexico -- Overview

- STPS does not have jurisdiction over labelling hazardous chemical products for the consumer or the general public
  - > The Secretariats of Economy, Health, or Environment have powers over product labelling





### **GHS** in Mexico -- Who Must Comply?

- Companies that have regulated chemicals requiring SDS, specifically
  - Companies in Mexico that use, handle, or store chemicals (substances or mixtures) for which SDSs are required
  - Foreign companies with business units, subsidiaries, or facilities in Mexico that use, handle, or store chemicals (substances or mixtures) for which SDSs are required
  - Companies in Mexico, or any other country, that sell or distribute chemicals (substances or mixtures) to firms in Mexico, and for which SDSs are required



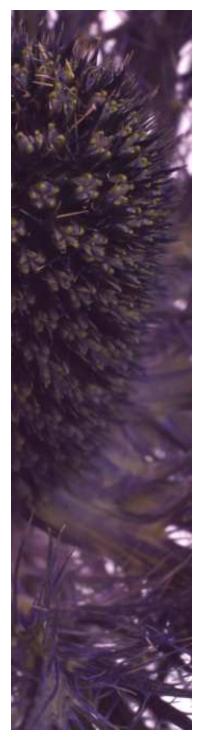
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### **GHS** in Mexico -- Section 1: Objective

■ To establish the requirements for "work centers" to have a harmonized system of identification of hazards and risks from dangerous chemical substances, to prevent "damages" to both the workers/employees and emergency response personnel



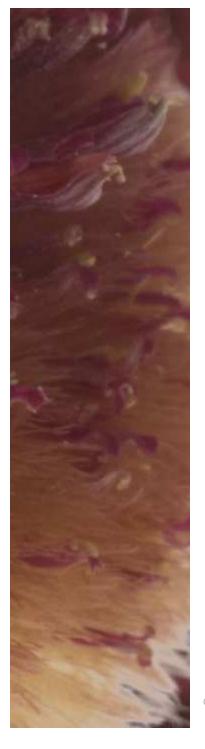




### GHS in Mexico -- Section 2: Field of Application

- States that NOM-018-STPS-2015 applies throughout Mexico, and specifically to all workplaces where dangerous chemical substances are handled
- Does NOT apply to:
  - Pharmaceuticals, food additives, cosmetics, and pesticide residues in food and hazardous waste
  - Cleaning products sold in supermarkets, caustic soda or hydrochloric acid for cleaning, and paints or insecticides for home use
    - For the last two items though, the Comisión Federal para la Protección Contra Riesgos Sanitarios (Mexican Federal Commission for the Protection Against Sanitary Risk, (COFEPRIS)) (the national sanitary agency) does require use of the GHS labels
- H and P phrases required





### GHS in Mexico -- Section 3: References

- Cites and incorporates by reference the following Mexican NOMs:
  - NOM-010-STPS-2014, Chemical agents polluting the work environment -- Recognition, evaluation and control
  - NOM-026-STPS-2008, Colors and signs of safety and hygiene, and identification of risks by fluids conducted in pipes
  - NMX-R-019-SCFI-2011, Harmonized System for the Classification and Communication of Chemical Hazards





### GHS in Mexico -- Section 4: Definitions

- Majority of definitions are standard, although some key ones to note:
  - ➤ "Labor authority" (4.2) -- The "competent administrative units of the Ministry of Labor and Social Welfare that carry out functions ... in matters of safety and health at work."
  - "Contractor" (4.10) -- "[T]he employer or employee outside the work center who temporarily works in it, and who is directly or indirectly involved with the process, and who because of their work can add or increase risk factors."
  - "Hydrogen potential" (4.40) -- "The concentration of hydronium ions, which represents the acidity or alkalinity of a substance, within a scale of 0 to 14."





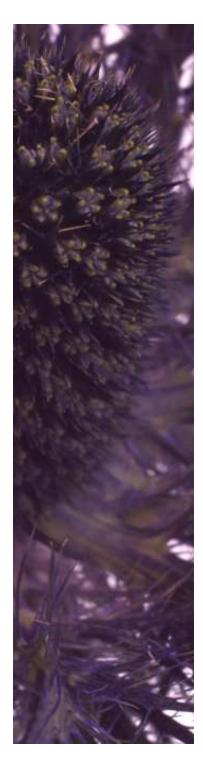
### **GHS** in Mexico -- Section 5: Acronyms or Abbreviations

- Again, some key ones to note:
  - VLE-PPT (5.19): "Time-weighted Average Exposure Limit Value"
  - > VLE-CT (5.20): "Short-term Exposure Limit Value"
  - VLE-P (5.21): "Peak Exposure Limit Value"



### **GHS** in Mexico -- Section 6: Obligations of the Employer

- Various aspects, most of which are similar to other global Health, Safety and Environment (HSE) management items
  - Implement NOM-018-STPS-2015
  - Have SDSs for all hazardous chemicals and mixtures in the workplace, and make available "permanently" to workers
  - Establish appropriate signage for "deposits, containers," shelves or storage areas" containing hazardous chemicals and mixtures
  - Inform and train all workers and contractors about SDS elements and signage
  - Deliver SDS for hazardous chemical substances and mixtures that they commercialize to customers







## GHS in Mexico -- Section 7: Obligations of Workers

- Participate in the implementation of NOM-018-STPS-2015 and related training
- Understand content and information on SDS, as well as signage
- Inform the employer regarding lack of SDS, tank, container, and storage area signage





## GHS in Mexico -- Section 8: Harmonized System for Identification and Communication of Hazards and Risks

- GHS in the workplace should include the following:
  - > The updated list of dangerous chemical substances and mixtures, where appropriate, that contain at least:
    - The name of the dangerous chemical or mixture;
    - The Chemical Abstracts Service (CAS) number for the substance and for the mixtures the CAS number of the components; and
    - The classification of their physical and health hazards, specifically related to their corresponding divisions or categories





## GHS in Mexico -- Section 8: Harmonized System for Identification and Communication of Hazards and Risks

- GHS in the workplace should include the following:
  - SDS for hazardous chemical substances and mixtures;
  - Signaling or labelling; and
  - The training provided to workers on the contents of SDS and signage

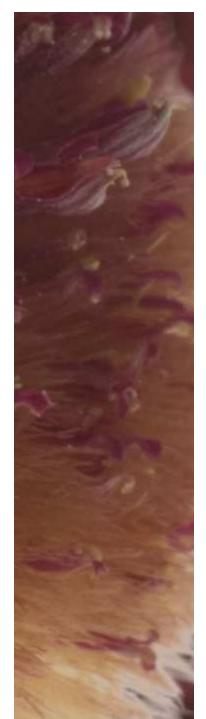


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#### **GHS in Mexico -- Section 9: SDS**

- Compliant GHS SDS shall:
  - > Be prepared in Spanish
  - Contain the sections listed in Section 9.2 of NOM-018-STPS-2015 (to be discussed later)
  - Include dangerous substances or mixture components with concentrations > specific composition limit values
    - Example: Serious eye injuries/eye irritation: > 1.0% (of mixture)



#### **GHS in Mexico -- Section 9: SDS**

- Compliant GHS SDS shall (cont'd):
  - Consider the additive effect of substances, for mixtures
  - Each section <u>must</u> be completed; acronyms such as ND (No Data) or NA (Not Available) may be used
  - Include the date of preparation and any subsequent revisions





### GHS in Mexico -- Section 10: Signaling

- Signage shall be placed in visible places on container, shelf, or work area
- Signage information must match SDS information
- Signage must be "marked, printed, painted [or] adhered" to the location, and be of "resistant and indelible material"
- Storage of the same type of hazardous material -signage can be in the area or on containers
- Storage of different types of hazardous material -signage must be on each of the containers or the parts of the shelves or area containing the same hazardous substance





### **GHS in Mexico -- Section 10:** Signaling

- The following items must be "signaled" (labeled):
  - > All containers of hazardous substances in process areas
  - > All containers in which hazardous substances are transported
  - > All "mobile containers of large dimensions" (e.g., rail cars) when it remains for 72+ hours outside the work center





### GHS in Mexico -- Section 10: Signaling

- Signage should include the following items:
  - > Name of the hazardous substance and mixture
  - Warning word, in accordance with Appendix A
  - Applicable pictograms/symbols
  - Hazard Identification Code, in accordance with Appendix C





#### **GHS** in Mexico -- Section 11: Training

- Provided to all workers involved with handling hazardous substances, members of the Safety and Hygiene Committee, and emergency response workers
- Shall be performed:
  - At least annually
  - Each time a new hazardous substance or mixture is introduced
  - When the attendant SDS or signage is updated





### **GHS in Mexico -- Section 12: Verification Units**

- List of accredited and approved units to assess compliance with NOM-018-STPS-2015
- Verification opinions valid for two years, ceteris paribus





### **GHS in Mexico -- Section 13: Procedure for Conformity Assessment**

- Detailed list of type of check(s) and documentation requirements to assess compliance with NOM-018-STPS-2015
- Example
  - Section 6.1 (employer must have GHS implemented in workplace)
- Verification is confirmed/documented by (specifically):
  - An updated list of hazardous substances and mixtures
  - The CAS number(s) for the hazardous substances and mixtures
- Section 13.4 mandates the number of workers to be interviewed, based on the total number of workers "occupationally exposed"





## **GHS in Mexico -- Section 14:** Transport

"Monitoring of compliance with this Standard corresponds to the Secretariat"





#### **GHS in Mexico -- Annexes**

- Annex A: Summary tables for classification and labelling
- Annex B: Labelling symbols, pictograms, and warning phrases
- Annex C: Hazard codes
- Annex D: Precautionary statement codes
- Annex E: Guide for SDS creation in a 16-Section format









### GHS in Mexico -- Section 9.2: SDS Section Headings

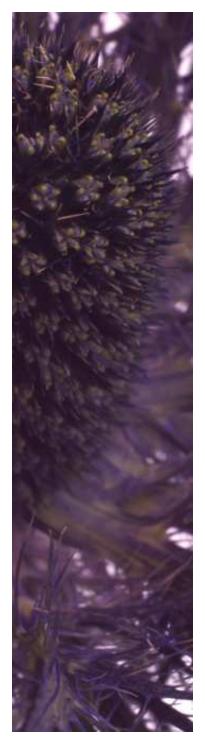
- SECTION 1: Identification of the dangerous chemical substance or mixture and the supplier or manufacturer
- SECTION 2: Hazards identification
- SECTION 3: Composition/information on ingredients
- SECTION 4: First aid measures
- SECTION 5: Fire-fighting measures
- SECTION 6: Spill or accidental release measures





### GHS in Mexico -- Section 9.2: SDS Section Headings

- SECTION 7: Handling and storage
- SECTION 8: Exposure controls/personal protection
- SECTION 9: Physical and chemical properties
- SECTION 10: Stability and reactivity
- SECTION 11: Toxicological information
- SECTION 12: Ecological information





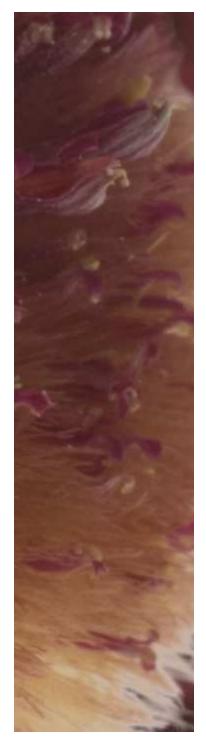
### GHS in Mexico -- Section 9.2: SDS Section Headings

SECTION 13: Disposal information

SECTION 14: Transport information

SECTION 15: Regulatory information

 SECTION 16: Other information, including information on the preparation and revision of SDSs





- No listings of substance classifications
- No methods for the classification of mixtures
  - > References NMX-R-019-SCFI-2011
    - NMX-R-019-SCFI-2011 adopts the classification methods for mixtures as written in GHS





- When skull and crossbones pictogram appears, the exclamation mark should not appear
- If corrosive pictogram appears, skin or eye irritation pictograms should not appear
- If health hazard pictogram appears to indicate sensitization hazard, the exclamation mark pictogram should not appear for skin sensitization, skin or eye irritation



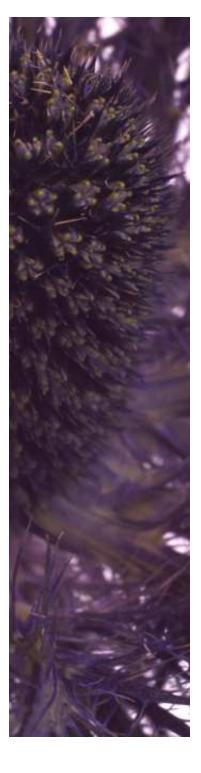


- NMX-019-SCFI-2011 requires GHS pictogram size of 100 x 100 mm red-bordered square set on point
- NOM-018-STPS-2015 sets minimum size based on distance from observer

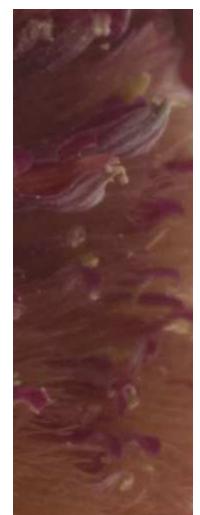
Measure from one side of the diamond (cm)	Minimum symbol height (cm)	Maximum distance observing the label (m)
3.1	2.5	To 7
6.2	50	Up to 15
12.5	7.6	Up to 23
18.7	10.1	To 30
25.0	15.2	To 60
37.5	30.2	Greater than 60

For distances less than 7 m, the employer must define the pictogram dimensions according to the size of the container or packaging -- must be legible





- Particular requirements for SDS
  - > Avoid using vague and ambiguous expressions
  - Avoid phrases such as "may be dangerous," "no health effects," "safe in most conditions of use," or "harmless"
  - Number all pages, indicating the total number of pages within it. For example: "page one of three" or "Page 1 of 3"
  - Indicate on each page the name of the substance or mixture





- Composition disclosure (Section 3)
  - Guidance states the following to be disclosed:
    - Substances: Stabilizing additives and impurities that contribute to substance classification must be reported
    - Mixtures: Components of hazardous substance must be reported in concentration/concentration range in mass or volume
  - When concentration range is provided, health hazard(s) reported must be of highest composition of each hazardous substance



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# Relationships to U.S. GHS (HCS 2012) and Canadian WHMIS 2015 Requirements

- Because NOM-018-STPS-2015 adopts the 5th Rev. GHS, the physical hazard classification category for aerosols is different from the HCS 2012 and the Canadian WHMIS 2015 standards
- NOM-018-STPS-2015 does not forbid using the "gases under pressure" classification together with the "aerosols" classification, therefore, both aerosol classifications may appear together on Mexican SDSs
- Ecological toxicity classification is required under NOM-018-STPS-2015; it is not mandatory under HCS 2012 and WHMIS 2015
- There is no separate classification criteria for "hazards not otherwise classified" or HNOC, as in HCS 2012 and the Canadian WHMIS 2015



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### **Concluding Thoughts**

- As of October 8, 2018, all three countries in North America will have implemented GHS in some form
- Mexico retains a unique "interpretation" of the Standard, so be cautious!
- Recall that STPS does not have jurisdiction over labelling, so check specific NOMs



#### **Thank You**

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