



## **GHS by Design: Using Pragmatic decisions to create SDSs/labels for multiple countries**

Carrie Decatur, Sr. Regulatory Analyst

# Human Nature



*It is human nature to tinker...*

*Carbeth – Kate Davies Designs*





## Hazard Classes

Choose which hazard classes to implement

Choose whether to add new classes

## Hazard Categories

Choose which categories to implement

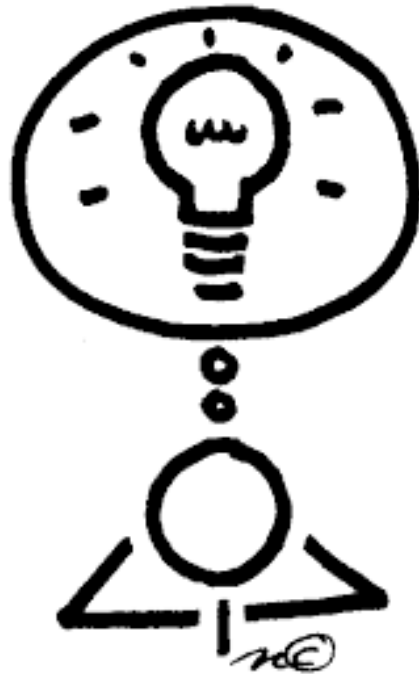
Choose sub-categories to implement

## Other requirements

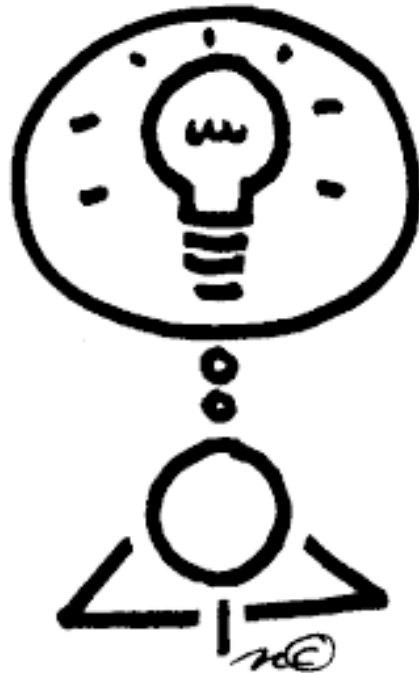
Choose cut-off limits for certain hazards

Determine whether to implement all notes included in the Purple Book

# How can this apply to us?



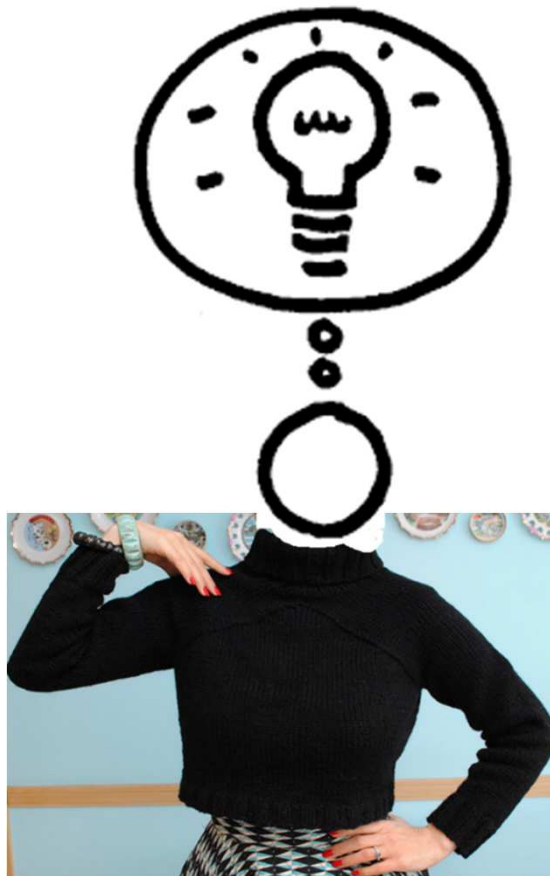
# How can this apply to us?



If countries can use a DIY method for implementing GHS...

**Then why can't companies do the same?**

# How can this apply to us?



If countries can use a DIY method for implementing GHS...

Then why can't companies do the same?

**Maybe we can change the way we look at the world and find areas of harmonization that will allow us to create regional SDS.**

# Changing the way we think

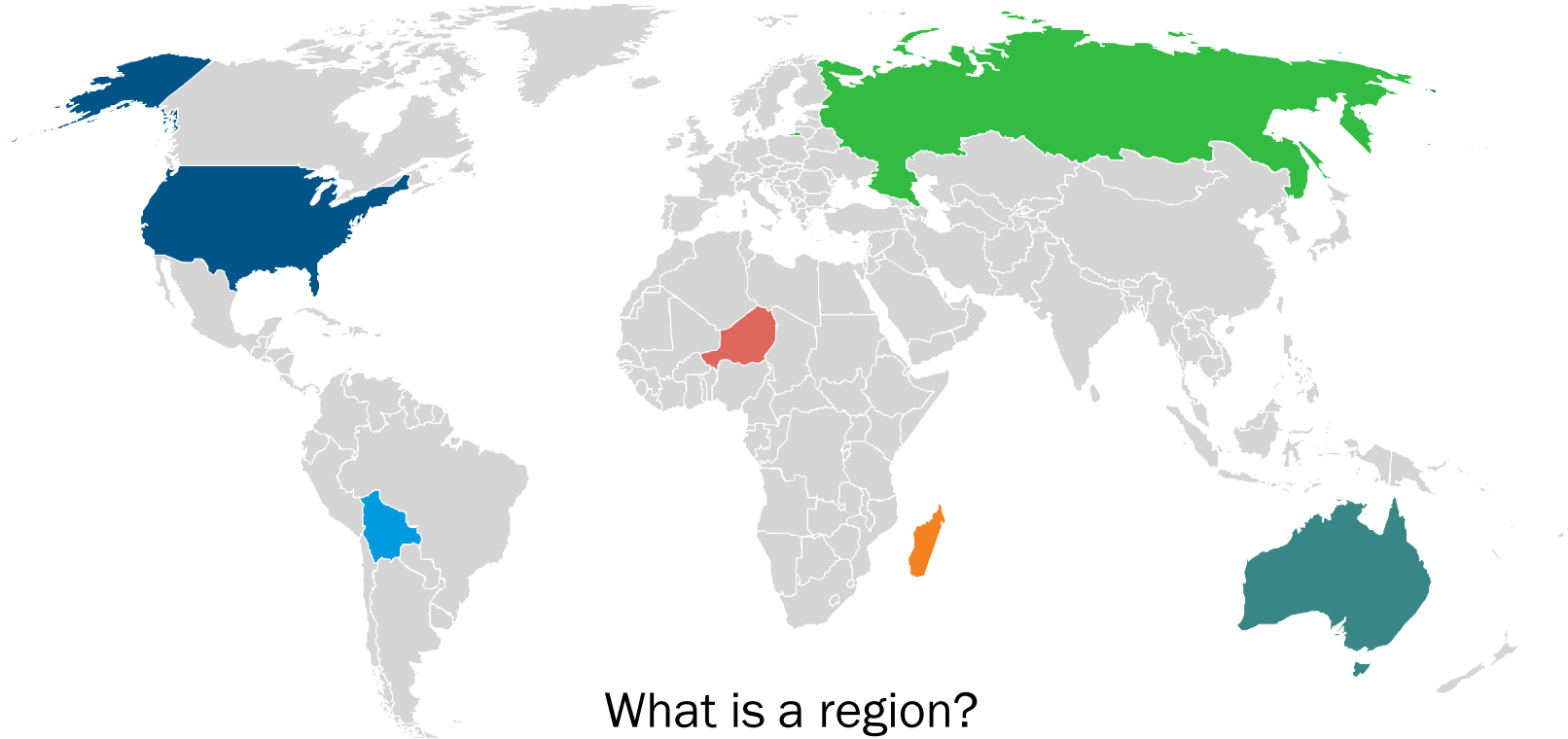


Going from spotting the differences



**To looking for the similarities**

# Changing the way we think



What is a region?

**When you change your thinking, a region could become any set of countries with a similar implementation.**



# Changing the way we think

## How do I know which region to create?

*The idea here is to create efficiencies in your authoring process; look for areas that will make your life easier*

---

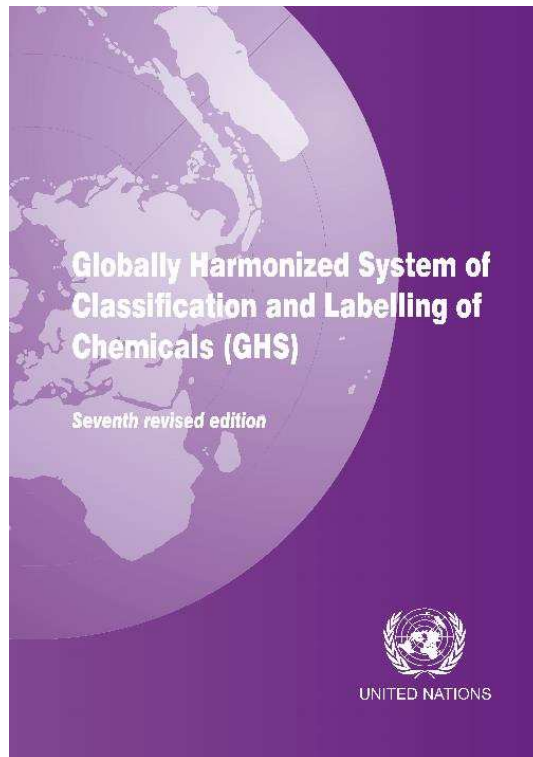
*Know which countries you are sending products into*

---

*Review specific country requirements to look for similarities*



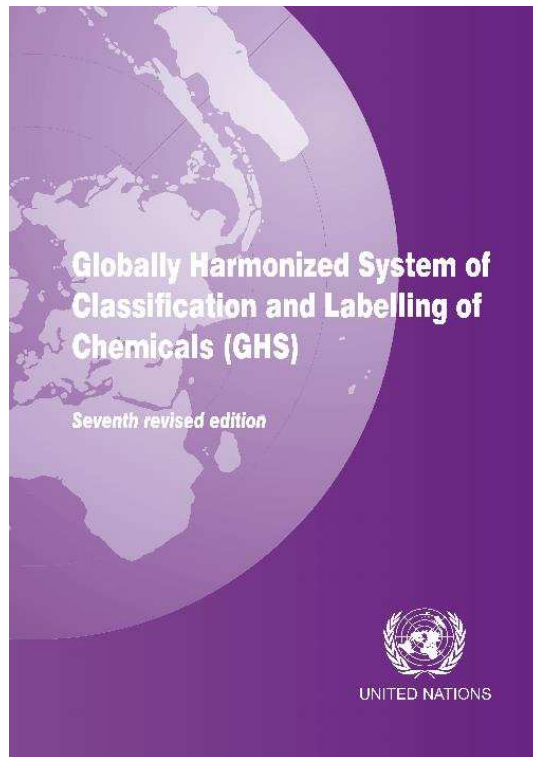
# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- Hazard classes
- Hazard categories
- Cut-off limits for sensitizers carcinogens, reproductive toxicity, STOT RE & SE
- Version of the H & P phrases to use
- SDS/Label format

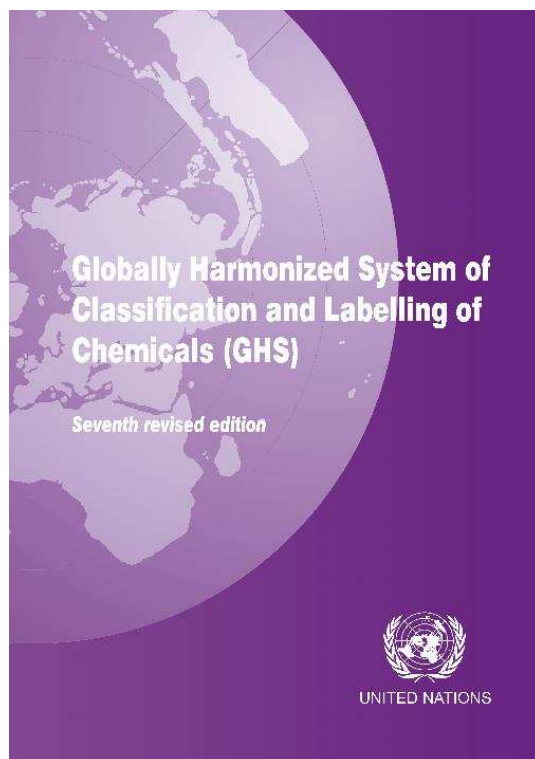
# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- Hazard classes
  - Generally due to differences in UN revisions
  - Environmental hazards

# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- Hazard categories
  - Acute toxicity – Category 5
  - Skin corrosion/irritation – Category 3
  - Flammable liquids – Category 4
  - Hazardous to the aquatic environment – acute – Categories 2-3
  - Aerosols – Category 3
  - Aspiration – Category 2

# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- Cut-off limits for sensitizers carcinogens, reproductive toxicity, STOT RE & SE

Table 3.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory sensitizer Category 1	≥ 0.1% (see note)	≥ 0.1% (see note)	..
Respiratory sensitizer Sub-category 1A	≥ 1.0%	≥ 0.2%	
Respiratory sensitizer Sub-category 1B	≥ 0.1%	≥ 0.1%	
Respiratory sensitizer Sub-category 1B	≥ 1.0%	≥ 0.2%	
Skin sensitizer Category 1	--	--	≥ 0.1% (see note)
Skin sensitizer Sub-category 1A	--	--	≥ 1.0%
Skin sensitizer Sub-category 1B	--	--	≥ 0.1%
Skin sensitizer Sub-category 1B	--	--	≥ 1.0%

Table 3.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that would trigger classification of the mixtures<sup>a</sup>

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≥ 0.1% (note 1)	..	..	..
	≥ 0.3% (note 2)			
Category 1B reproductive toxicant	--	≥ 0.1% (note 1)	..	..
	--	≥ 0.3% (note 2)		
Category 2 reproductive toxicant	--	--	≥ 0.1% (note 3)	..
	--	--	≥ 3.0% (note 4)	
Additional category for effects on or via lactation	--	--	--	≥ 0.1% (note 1)
	--	--	--	≥ 0.3% (note 2)

Table 3.8.2: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2<sup>a</sup>

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target organ toxicant	≥ 1.0% (note 1)	1.0 ≤ ingredient < 10% (note 3)
	≥ 10% (note 2)	
Category 2 Target organ toxicant	--	≥ 1.0% (note 4)
	--	≥ 10% (note 5)

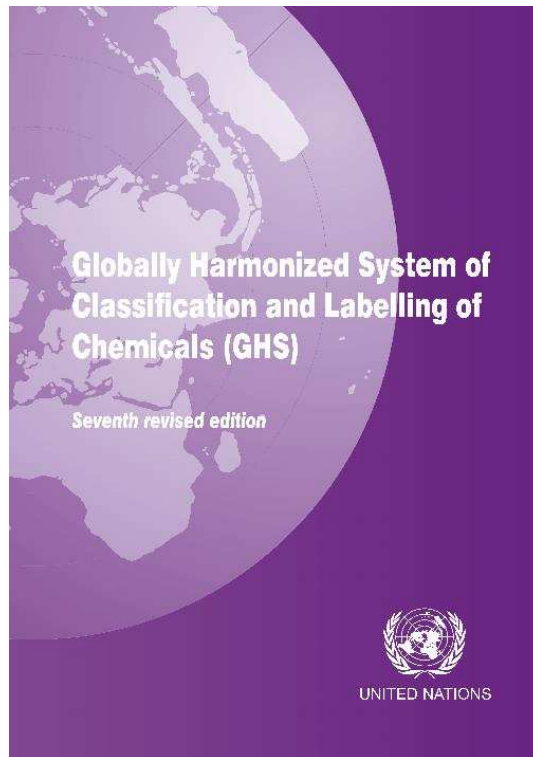
Table 3.9.3: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture<sup>a</sup>

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target organ toxicant	≥ 1.0% (note 1)	1.0 ≤ ingredient < 10% (note 3)
	≥ 10% (note 2)	1.0 ≤ ingredient < 10% (note 3)
Category 2 Target organ toxicant	--	≥ 1.0% (note 4)
	--	≥ 10% (note 5)

Table 3.6.1: Cut-off values/concentration limits of ingredients of a mixture classified as carcinogen that would trigger classification of the mixture<sup>a</sup>

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≥ 0.1 %	--	..
Category 1B carcinogen	--	≥ 0.1 %	
Category 2 carcinogen	--	--	≥ 0.1% (note 1)
	--	--	≥ 1.0% (note 2)

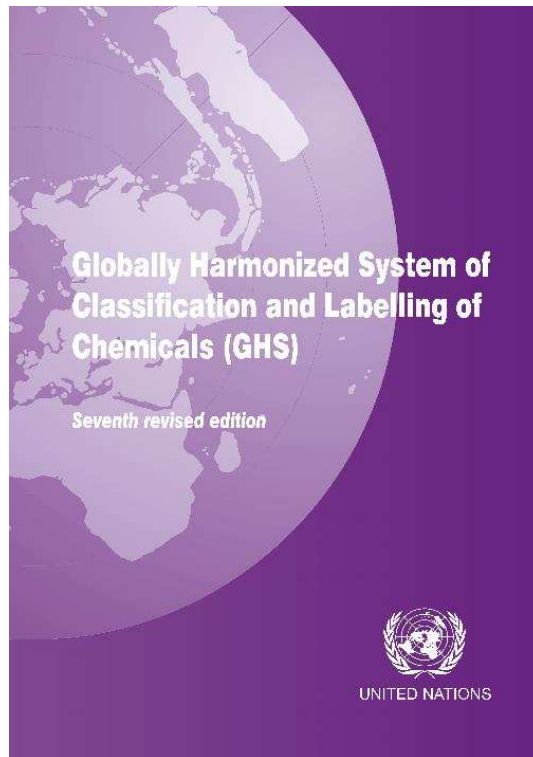
# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- Version of the H & P phrases to use
  - The building blocks and phrases may not always look like they are from the same revision
    - S. Korea MOEL 2016-19: Implemented revision 4, but the building blocks selected look more like revision 3
    - OSHA HazCom 2012: Implemented revision 3, but phrases match revision 4

# General areas of inconsistency in GHS



## Areas of potential differences within the UN GHS framework:

- SDS/Label Format
  - Are sub-headers required to be numbered or be in a certain order?
  - Are there other regulations which have label requirements?
  - Translations

# Changing the way we think



Take inventory of the hazards applicable to your products

**If your products only fall into certain categories, you may be able to find even more similarities across regions**

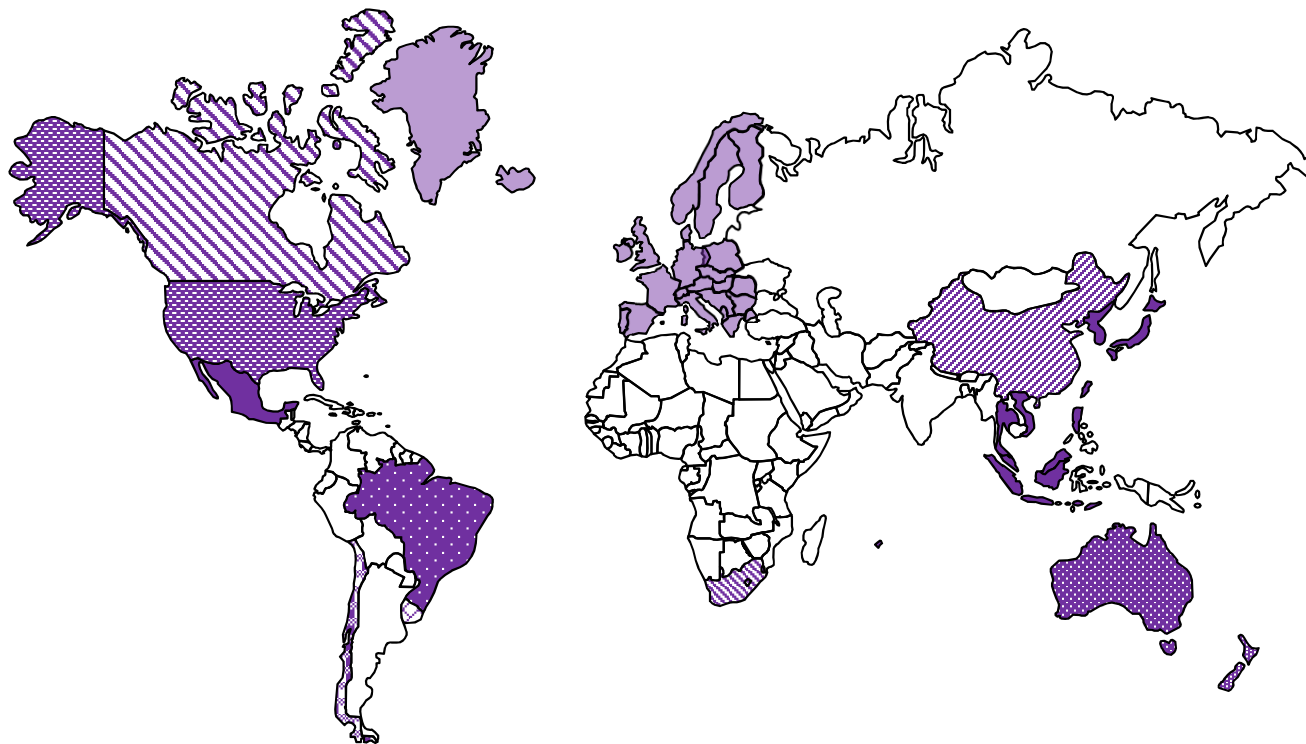




# Changing the way we think



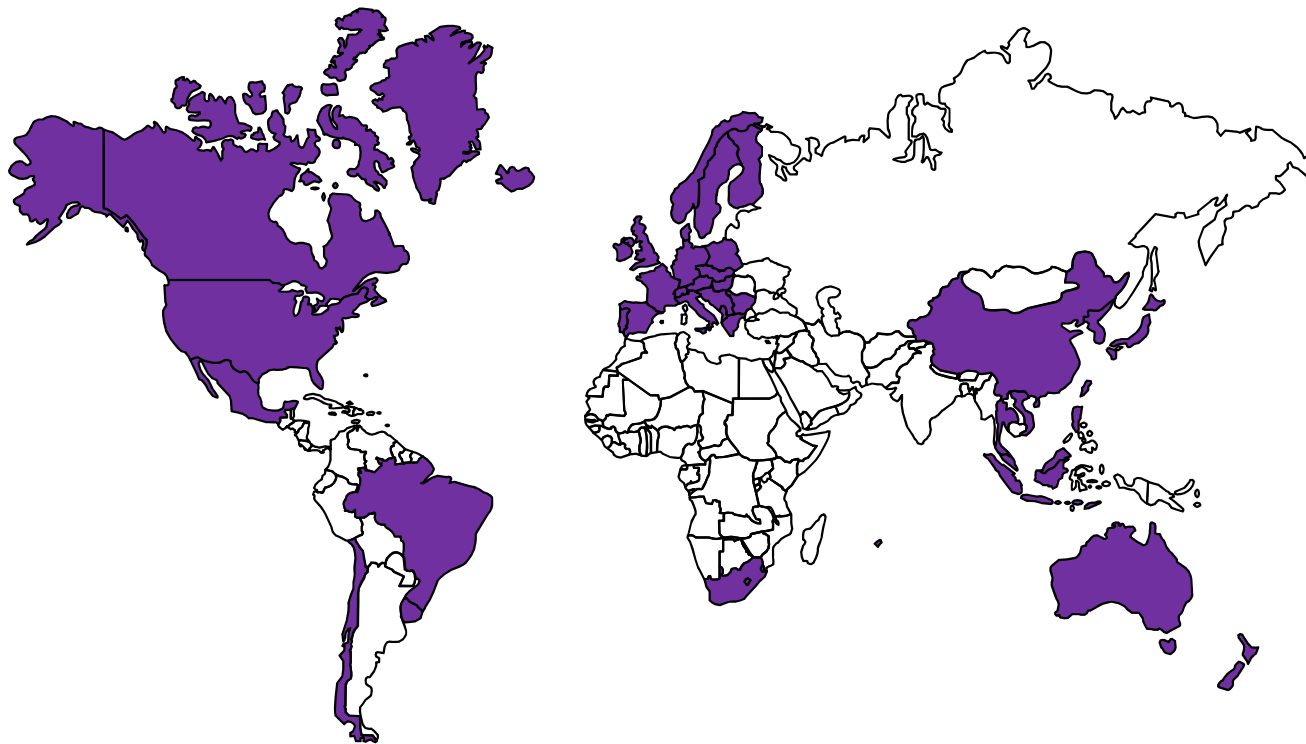
Can we make **this** map look more like



# Changing the way we think



Can we make this map look more like **this**?



# Changing the way we think



Building blocks are the one of the main contributors to the differences in classification

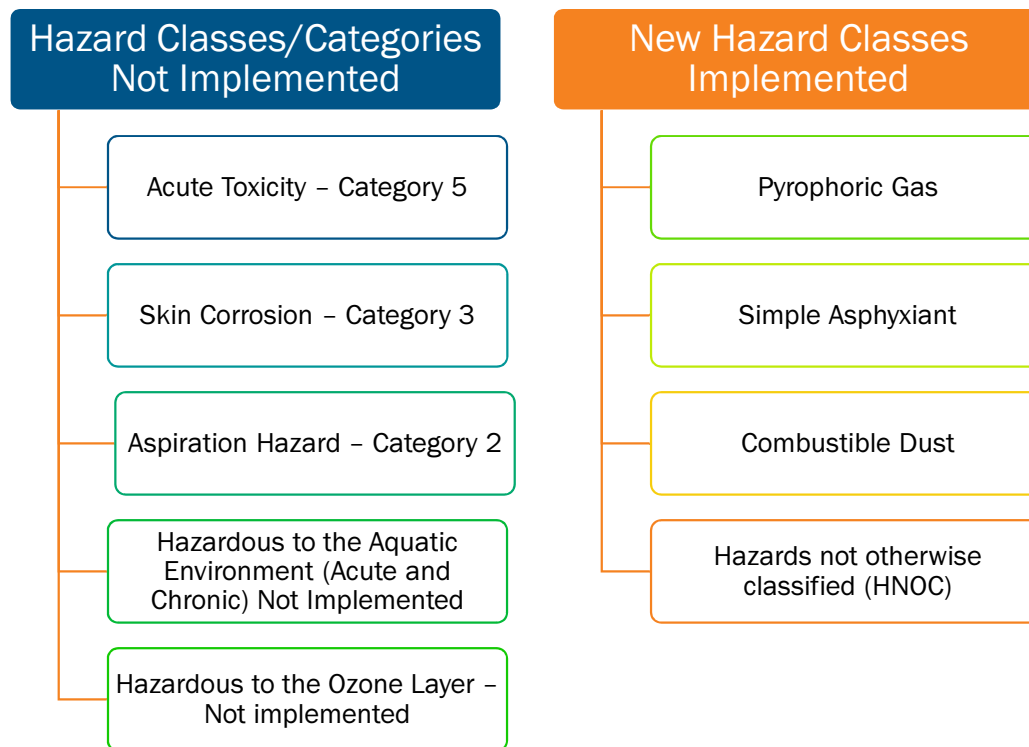


However, if your products don't fall into classifications that cause the differences, then do those differences matter?

# Changing the way we think



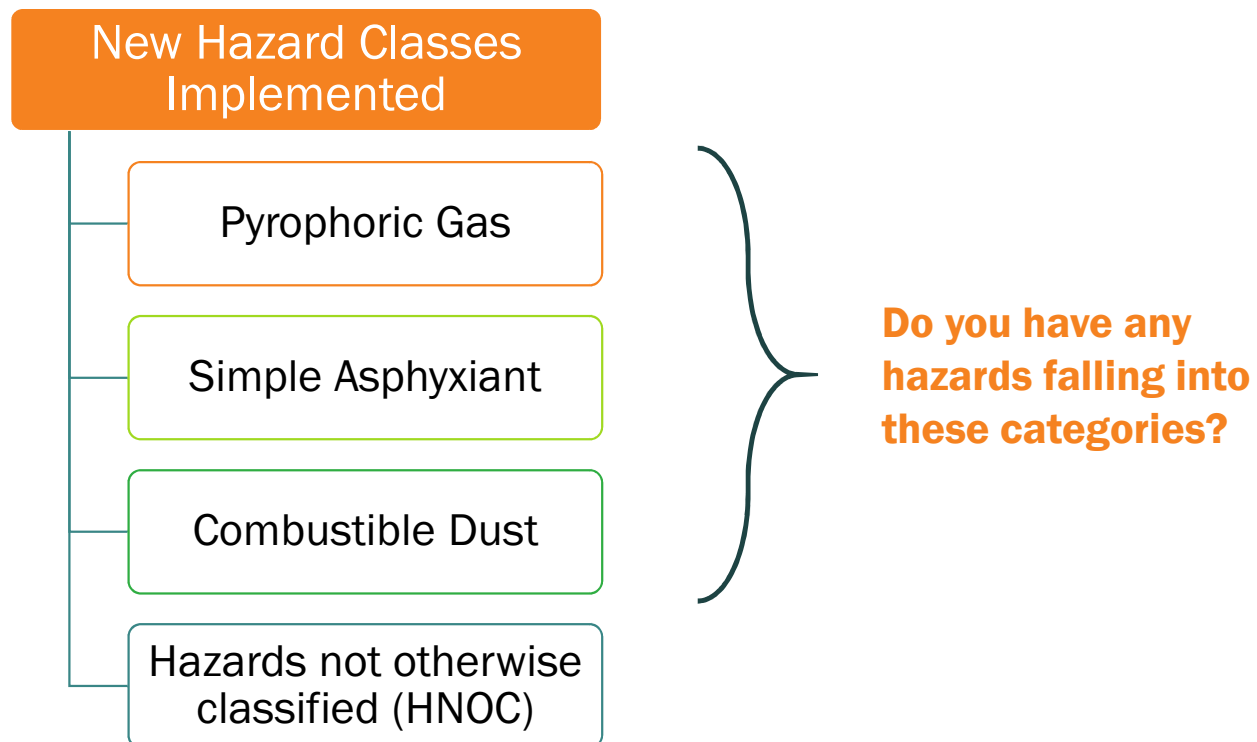
## Differences between **OSHA HazCom** and **UN GHS Rev 3**



# Changing the way we think



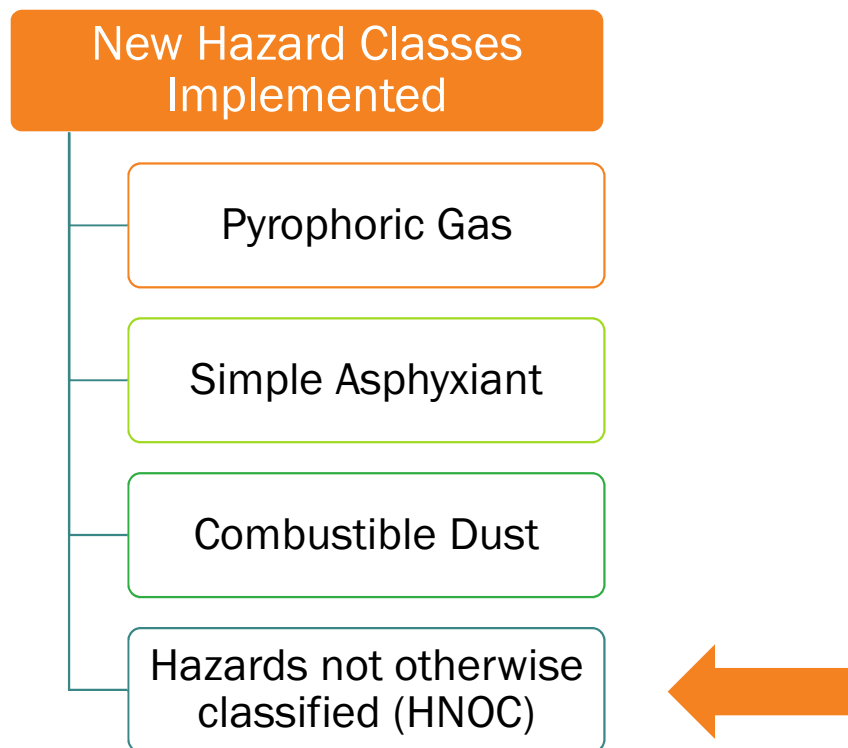
## Differences between **OSHA HazCom** and **UN GHS Rev 3**



# Changing the way we think



Differences between **OSHA HazCom** and **UN GHS Rev 3**



# Changing the way we think



## From UN GHS revision 7:

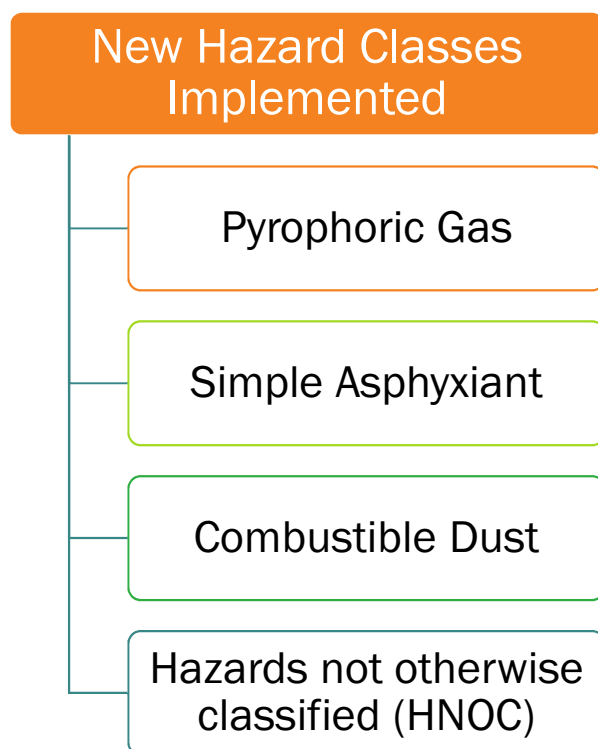
### A4.3.2.3 *Other hazards which do not result in classification*

Provide information on other hazards which do not result in classification but may contribute to the overall hazards of the material, for example, formation of air contaminants during hardening or processing, dust explosion hazards, suffocation, freezing or environmental effects such as hazards to soil-dwelling organisms. The statement “May form explosible dust-air mixture if dispersed” is appropriate in the case of a dust explosion hazard.

# Changing the way we think



## Differences between **OSHA HazCom** and **UN GHS Rev 3**



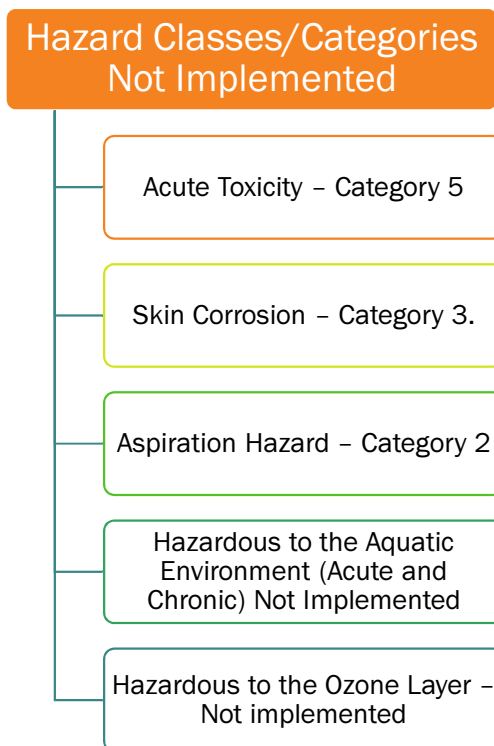
**This is really applicable to all GHS implementations.**



# Changing the way we think



## Differences between **OSHA HazCom** and **UN GHS Rev 3**



- Matching GHS implementations?
- Pragmatic decisions?

# How this might work



The balancing act

**Pragmatic decisions,  
marketing, risk, compliance**

# How this might work



## Pros

Process efficiencies

Fewer SDSs to maintain

## Cons

Additional classifications shown

Competitive disadvantage



## Decision criteria:

- Compliance is key
- Can you live with additional categories?
  - Acute Toxicity – Category 5
- Can you live with additional Hazard Classes?
  - Environmental Hazards
- Can you live with lower classification cut-off limits?

# Are you ready to try it out?



**Argentina**

- References UN GHS Rev 5 for all implementation details



**China**

- Revision 4 building blocks and phrases
- Additional requirements for the SDS



**Taiwan**

- Revision 4 building blocks and phrases
- Hazardous to the Aquatic Environment based on Revision 2

*Are you ready to try it out?*



**Argentina**



**China**



**Taiwan**

## **Differences between UN GHS Rev 4 & Rev 5:**

- Changes in P-phrase assignments/text
- Re-write of certain sections for clarity
- Re-organization of appendices
- Additional test methods added
- No new hazard classes or categories added

*Are you ready to try it out?*



**Argentina**



**China**



**Taiwan**

## Differences between UN GHS Rev 4 & Rev 5:

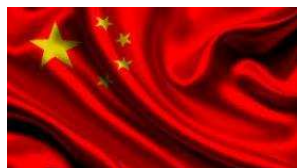
- **Changes in P-phrase assignments/text** ←
- Re-write of certain sections for clarity
- Re-organization of appendices
- Additional test methods added
- **No new hazard classes or categories added**

# Are you ready to try it out?



**Argentina**

- Building blocks implemented:
  - For all three countries, all hazard classes and categories have been implemented



**China**

- Cut-off Limits (Sensitizers, Carcinogens, Reproductive Toxicity, STOT – RE & SE)
  - No details were given by any of the countries on which cut-offs to use



**Taiwan**

- Other Classification issues
  - When Taiwan updated to revision 4, they did not implement the standard for hazardous to the aquatic environment
  - Based on UN GHS Revision 2





# Are you ready to try it out?



**Argentina**



**China**



**Taiwan**

- SDS Requirements:
  - Argentina and Taiwan use a standard GHS SDS
  - China's GB/T 17519-2013 has included additional requirements, for example:
    - Section 2 - Emergency overview, additional physical, health and environmental hazard information
    - Section 14 - Additional transport precautions
- Label requirements:
  - Combined label?
  - China
    - Ingredient disclosure
    - Reference to SDS
  - Taiwan
    - Must indicate when a component is an EPA toxic substance
      - Disclosure requirement
      - Statement: Toxic Substance
  - Translations



# Are you ready to try it out?



**Argentina**



**China**



**Taiwan**

## Summary

- China's GB/T 17519-2013 has included additional requirements, for example:
  - Section 2 – Emergency overview, additional physical, health and environmental hazard information
  - Section 14 – Additional transport precautions
- When Taiwan updated to revision 4, they did not implement the standard for hazardous to the aquatic environment
  - Based on UN GHS Revision 2
- Changes in P-phrase assignments/text
- Label requirements:
  - China
    - Ingredient disclosure
    - Reference to SDS
  - Taiwan
    - Must indicate when a component is an EPA toxic substance
    - Disclosure requirement
    - Statement: Toxic Substance
- Translations

# Choose your own adventure



You are likely to have more success with countries that did not have mature hazard communication systems prior to GHS

---

Determine what you won't be flexible on and then start there when comparing regulations



i.e. If you definitely do not want a Carcinogen – Category 2 classification to show at 0.1% unless required, match cut-off values first

---

The format of the label may have to be different, but if the classification and information driven by the classifications is the same, you've already made your life easier

---

Document everything!

