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How to keep regulatory data and documents up to date

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Intro / Background

- Advanced degrees in Chemical Engineering & Chemical Physics
- 8 years university teaching experience (chemistry & physics)
- 20 years industrial experience (pulp & paper, glass, lubricants)
- 15 years experience as an SDS author and consultant.

Currently:

- Train & support users of CHEMDOX SDS Authoring software (North America, Europe and Australia)
- Provide additional regulatory consulting services through my company, Global Safety Data.

Presentation Intent

Keeping regulatory data and documents up to date is challenging!

Specific challenges:

- Continually changing national & international regulations
- Production changes & new product development
- Marketing & business demands
- Practical concerns (like when to update documents)

This presentation discusses these challenges and how to handle them, including strategies and tools that can help

Outline

- Quick overview of regulatory requirements and challenges
  - International, national & local regulations
  - Marketing demands & business concerns
  - Enforcement & other challenges
- Ways to approach these challenges
  - Case study - US HCS 2024 Transition
  - Case study - Product reformulation
- Summary & conclusions

Types of documents

EHS professionals contribute to many kinds of data & documents:

- Safety Data Sheets
- Labels & Technical Data Sheets
- Transport documents
- Worker protection instructions
- C&L, PCN, PMN submissions
- SARA & other regulatory reports, etc.

This presentation will focus mainly on SDS's & Labels
Principles apply to other types of data & documents

Overview of SDS Requirements

To be in compliance, Safety Data Sheets & Labels need to:

- Meet country-specific regulatory requirements
- Use the required language(s), format & wording
- Include sufficient & reliable information in all 16 sections
- Be consistent with hazard classifications in that country
- Be consistent with each other and with supporting documents

Many things to pay attention to … and even if these are handled now, regulatory and other changes will require adjustments later

Challenges

Fundamental Challenge – System not harmonized

"Globally Harmonized System" is not completely harmonized.

Some things standardized (e.g. pictograms), but countries use:

- Different GHS-UN revisions & country-specific implementations
- "Required" or "recommended" chemical classifications
- Different requirements in different industries / segments
- Inconsistent requirements, even within same country

… and these requirements change over time!

GHS Revisions & Implementations

Countries implement GHS & transport regulations differently

- 11 different GHS Revisions, with at least 8 in current use
- Country-specific implementations – some countries don't use:
  - Environmental hazards
  - Combustible Dust hazards
  - Acute Toxicity Category 5
- Cutoff & concentration limit variations for same hazard categories
- State or county-level regulations (e.g CARB)

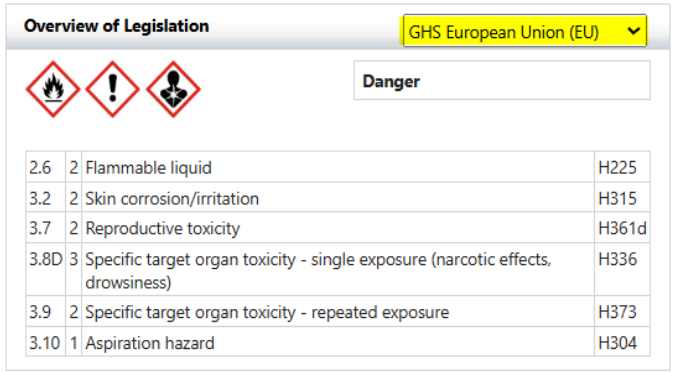
… and these regulations change over time!

“Required” chemical classifications

Some countries have “required” classifications for chemicals

Example: Toluene

EU CLP (required)

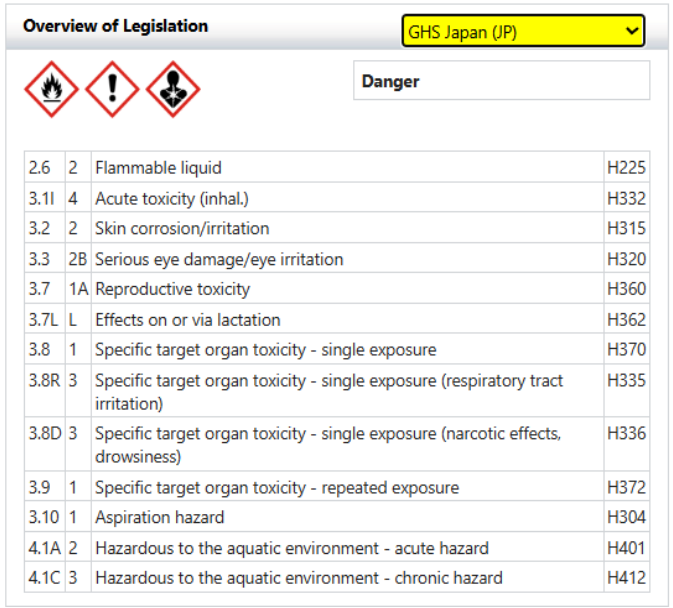


Overview of Legislation — GHS European Union (EU)

Danger

2.6	2	Flammable liquid	H225
3.2	2	Skin corrosion/irritation	H315
3.7	2	Reproductive toxicity	H361d
3.8D	3	Specific target organ toxicity - single exposure (narcotic effects, drowsiness)	H336
3.9	2	Specific target organ toxicity - repeated exposure	H373
3.10	1	Aspiration hazard	H304

Japan (not required)



Overview of Legislation — GHS Japan (JP)

Danger

2.6	2	Flammable liquid	H225
3.1I	4	Acute toxicity (inhal.)	H332
3.2	2	Skin corrosion/irritation	H315
3.3	2B	Serious eye damage/eye irritation	H320
3.7	1A	Reproductive toxicity	H360
3.7L	L	Effects on or via lactation	H362
3.8	1	Specific target organ toxicity - single exposure	H370
3.8R	3	Specific target organ toxicity - single exposure (respiratory tract irritation)	H335
3.8D	3	Specific target organ toxicity - single exposure (narcotic effects, drowsiness)	H336
3.9	1	Specific target organ toxicity - repeated exposure	H372
3.10	1	Aspiration hazard	H304
4.1A	2	Hazardous to the aquatic environment - acute hazard	H401
4.1C	3	Hazardous to the aquatic environment - chronic hazard	H412

… and these classifications change over time!

Cut-off & concentration variations

Cut-off and concentration limits vary by country, for same hazard

Examples:

- Resp. & Skin Sens: Limits = 0.01%, 0.1%, 0.2% or 1%
- Acute Tox, Cat. 1-3: Limits = 0.1% or 1%
- Carcinogenicity 2: Limits = 0.1% or 1%

… and these requirements can change over time!

Inconsistency within a country

Inconsistent regulatory requirements within a single country

Examples:

- US Env. Hazards: DOT requires, OSHA does not
- EU: Requirements vary by industrial setting and use
- Philippines: GHS Rev. 4, except for "household" products (Rev. 8)

… and these requirements can change over time!

Change over time

Regulations change over time, within same country or jurisdiction

Examples:

- EU: About 2 ATP's / year. In 2023, 56 new "Fragrance Allergens"
- US: Switching from GHS Rev. 3 to Rev. 7 by Jan. 2026
- Canada: Switching from GHS Rev. 5 to Rev. 7 by Dec. 2025
- Other national, state & local regulations change over time

New documents required even when product remains the same.

Example – EU 2020/878 requires:

- Adding ingredient ATE's and aquatic hazard "multiplying factors"
- Listing sensitizers that are present at 1/10th of their SCL
- Various wording and format changes

New Business Requirements

Additional challenges due to manufacturing and business concerns:

- New information from Raw Material suppliers (e.g. EU Allergens)
- Product reformulation & new product development
- Raw material variability and availability (e.g. Supply limitations)
- Efficiency & cost concerns (e.g. Cheaper sources)
- Marketing demands (e.g. “Consumer friendly” products, etc.)

… and these requirements can change over time

What about ...

- US HCS 2024 vs Canada's WHMIS 2022?
- Required wording changes? (e.g. Brasil header)
- OEL changes - How to keep track?
- Changes in labeling & transportation requirements?
- Tiny labels & reduced packaging? (e.g. EU, Chile)
- Changes in regulatory enforcement?
  … and many more!

All of these can impact regulatory data & documents

SDS Compliance Checks

SDS's & Labels are often subject to "Compliance checks".

- Industry-specific. Can be manual or automated
- Often incorporate new or future regulatory changes

Documents that worked before may not meet new requirements

Examples:

- Shipping & Logistics companies (DHL, FedEx, OTR, etc.)
- Online sales companies (Amazon, Walmart Marketplace)
- European Automobile Manufacturer's Association:
  https://www.acea.auto/files/AIG_V4.0_Annex_Q-SDS_Compliance_Checks_2021-EN.pdf

Keeping Data & Documents Up-To-Date

Need ways to track and manage these issues, where relevant
… and especially how they change over time!

Where to go for help?

- Public Regulatory bodies (e.g. ECHA, OSHA)
- Private Regulatory & Legal Consultants
- SDS & Label Authoring Software
- Industry Groups
- Product Experts

Many resources here at the Annual Meeting!

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Case Studies - Introduction

How to approach case studies (1)

As we go through case studies, look for the common ideas:

- Understanding the challenge
- Focusing on the key issues
- Developing a strategy
- Getting tools & support
- Resolving the problem

How to approach case studies (2)

Your situation is unique. Ask yourself:

- How do these ideas apply to my own challenges?
- What tools and support do I need for my personal situation?
- Where can I get the help that I need?

Many resources here at the Annual Meeting can help!

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Case study

Update to US HCS 2024

Update to HCS 2024 (1)

Situation: HCS 2024 becomes mandatory in Jan. 2026

- Switching from GHS Rev. 3 to Rev. 7 (with modifications)
- All SDS's and many labels need to be updated
- Some production changes may be needed

Requirements:

- Identify products where GHS & transport hazards will change
- Identify changes early, to smooth transition process
- Need to check all products, over time

Update to HCS 2024 (2)

Key Issues & Constraints:

- Need to identify products with classification changes early
- Limited EHS resources, need to focus on “urgent” situations first
- Need to keep existing & documents unchanged until ready

External deadlines:

- Substances: New documents needed by January 2026
- Mixtures: New documents needed by July 2027

Needed: Tools to predict HCS 2024 classification changes

Update to HCS 2024 (3)

Strategy - Substances:

- Find/develop tools to quickly predict classification changes
- Use tools to focus first on substances with significant changes
- Create new SDS’s & labels for relevant substances by Jan 2026

Strategy - Mixtures:

- If substances don't change, mixtures won't change
- For substances with changes, identify affected mixtures
- Use tools to determine classification changes
- As needed, adjust SDS's, labels, transport documents

Update to HCS 2024 (4)

Substance Analysis:

Substance Name	CAS #	Characterization	Required Updates
Citric acid	77-92-9	Organic acid	GHS-US, DOT
Limonene	5989-27-5	Organic acid	GHS-US, DOT
Isopropylcyclohexane	696-29-7	Aliphatic solvent	GHS-US

Mixture Analysis:

Mixture Name	Part #	Affected substances	Required Updates
Sparkle Cleaner – Citrus	SC-1242	Citric acid	GHS-US, DOT
Sparkle Cleaner – Citrus	SC-1242	Limonene	GHS-US, DOT
Painter's Pal	PP-3804	Isopropylcyclohexane	GHS-US

Update to HCS 2024 (5)

Action steps:

- Use mixture analysis to determine next steps
- Adjust SDS's, labels & transport documents as needed
- Initiate production changes, where appropriate

Benefits:

- Identifying affected mixtures early reduces effort and costs
- EHS involved "up-front", so easier to keep regulatory data and documents up to date

And that's not all!

Production changes can affect your regulatory work ...

- Changes in raw materials, suppliers
- Product development, new product lines, etc.

... and Regulatory changes can affect your actual production ...

- New information on supplier SDS's (e.g EU Fragrance Allergens)
- Changes due to other regulatory restrictions

Regulatory work is inextricably linked to production changes
... and EHS may be involved in unexpected ways

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Case study

Product Reformulation

Product Reformulation (1)

Situation: Due to regulatory changes, I need to reformulate my product. EHS is asked to suggest less hazardous formulas

Requirement: Create a product formula that reduces the hazards, while keeping development costs low.

Key Issues & Constraints: Product reformulation needs to

- Meet the technical specifications.
- Minimize the classification hazards
- Minimize development time & testing costs

Product Reformulation (2)

Strategy:

- Work with experts to identify minimum required concentrations
- For hazardous ingredients, determine hazard cut-off limits
- Propose trial formulas using concentrations below cut-off limits
- Formulate & test trial formulas vs. technical requirements

Support & Tools:

- Tools to calculate hazard cut-off limits for required chemicals.

Product Reformulation (3)

Strategy ("Painter's Pal"):
Required ingredients: Toluene (>5%), Pentylcyclohexane (>8%)

Method: Use GHS “Bridging Principles” to estimate hazards for various ingredient concentrations without actual test data

Tools: Software to calculate hazard cutoffs based on ingredient concentrations

Product Reformulation (4)

Toluene hazard cutoffs at 0.1%, 1%, 2.5%, **10%, 20%**, 25%

Minimum concentration = 5%. Trial concentrations: 9% & 19%

Skin Damage / Irritation	Cutoff
Cat. 1 (Damage)	NA
Cat. 2 (Irritation)	>10%
Acute Aquatic Toxicity	**Cutoff**
Cat. 1	NA
Cat. 2	>25%
Cat. 3	>2.5%
Aspiration Toxicity	**Cutoff**
Cat. 1	>10%

Reproductive Toxicity	Cutoff
Cat. 1	NA
Cat. 2	>0.1%
STOT Single Exp.	
Cat. 3	>20%
STOT Repeat Exp.	**Cutoff**
Cat. 1	NA
Cat. 2	>1%

Product Reformulation (5)

Pentylcyclohexane hazard cutoffs at 0.25%, 2.5%, **10%, 25%**
Minimum concentration = 8%. Trial concentrations: 9% & 24%

Acute Oral Toxicity	Cutoff
Cat. 1	NA
Cat. 2	NA
Cat. 3	NA
Cat. 4	>25%
Cat. 5	>10%
Eye Damage / Irritation	**Cutoff**
Cat. 1 (Damage)	NA
Cat. 2 (Irritation)	>10%

Acute Aquatic Toxicity	Cutoff
Cat. 1	>25%
Cat. 2	>2.5%
Cat. 3	>0.25%
Chronic Aquatic Toxicity	**Cutoff**
Cat. 1	>25%
Cat. 2	>2.5%
Cat. 3	>0.25%

Product Reformulation (6)

Proposed test levels to reduce hazards:

- Toluene (T): 9% & 19%
- Pentylcyclohexane (PCH): 9% & 24%

Four mixture combinations to test:

9% T, 9% PCH
9% T, 24% PCH
19% T, 9% PCH
19% T, 24% PCH

Product Reformulation (7)

Action steps:

- Propose mixtures with less toluene & pentylcyclohexane
- Have mixtures tested against required technical specifications
- Identify best options, and implement in production

Benefits:

- Reduces development costs during product reformulation.
- EHS involved “up-front”. Easier to update needed documents and keep regulatory information up to date.

Summary & Conclusions

Summary & Conclusions

- Keeping data & documents up to date can be very challenging

- … But these challenges can be handled by:
  - Understanding the challenge
  - Focusing on the key issues
  - Developing a strategy
  - Getting the necessary tools & support
  - Taking appropriate actions

- Many resources available to help meet these challenges!
  (SCHC courses & meetings, software & support companies, etc.)

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Questions?


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