Best practice measures to be considered for EU CLP compliance focusing on CLP classification of Mixtures

欧州CLP規則対応の優良事例を目指して（混合物のCLP分類を中心に）

Classification, Labeling and Packaging

GHS&Risk Labo.
GHS&Risk研究会

Jun Yamaguchi

September 9, 2010

Introduction	はじめに
UN GHS	国連GHS
CLP outline	CLP概要
Measures needed	必要な対応手段

Introduction はじめに

UN GHS 国連GHS

CLP outline CLP概要

Measures needed 必要な対応手段

Current Situation: Turning Point

現在の状態：踊り場

- ”2020 goal” of SAICM is demanding new legislations for “Sound Management of Chemicals”

SAICMの2010年目標に、新規の化学物質管理法が要請されている

Limited Management
限定された管理

New Laws Demanding precise hazard communication And sound Management
より正確なハザード情報の提供としっかりした化学物質管理を求める法の出現

Introduction　はじめに

Difficulties to be overcome: language, tons of documents, complexity, tracking dynamic change

課題：言語、多くの文書、複雑さ、急速な変化への追従

UN GHS　国連GHS

CLP outline　CLP概要

Requirement for SDS　SDS要求事項

Measures needed　必要な対応手段

GHS

- Globally harmonized system of classifying and labeling chemicals that was recommended by the United Nations in 2003

平成１５年（２００３年）７月に国連より勧告された世界的に統一されたルール

Short history of GHS

ＧＨＳの歴史

- **1990:** ILO adopted a Convention (Convention No. 170) and a Recommendation (Recommendation No.177) concerning *GHS*
  ＩＬＯで化学物質に関する条約（１７０号）及び勧告（１７７号）を採択
- **1992:** UNCED adopted Chapter 19 (Environmentally sound management of toxic chemicals…) of Agenda 21
  国連環境開発会議（UNCED）でアジェンダ２１を採択。（第１９章にＧＨＳに関する「化学品の適正な管理」）
- **2002:** WSSD in Johannesburg encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008.
  ヨハネスブルグサミットで各国に２００８年までに完全実施を奨励することが採択された。

Technical work by three focal points

3方面での技術開発

- **Physical hazards**; UN Sub-Committee of Experts on the **Transport of Dangerous Goods** (**UNSCETDG**)

  物理化学的危険性：国際輸送規則の小委員会

- **Health and environmental hazards**; **OECD**

  健康有害性：OECD

- **Hazard communication**;**ILO**

  Hazard communication issues include label elements and information on Safety Data Sheets (SDS)

  危険有害性の情報伝達(SDS,ラベル)：ILO

GHS revision history

GHS改訂履歴

- UNSCEGHS has a **2 year work-programme to update and amend** the GHS text GHSは2年毎に改訂される
- Revisions and topics 改訂履歴とトピックス
  - **First edition : 2003** 初版
  - **First revised edition : 2005** 改訂１版
  - **Second revised edition : 2007** 改訂２版

    Base edition of EU CLP（欧州CLPはこの改訂２版が基準）
    - **codification of hazard and precautionary statements** 危険有害性情報・注意書きのコードができた
  - **Third revised edition : 2009** 改訂３版
    - **new hazard class, hazardous to the ozone layer (Already incorporated in EU CLP)**
      オゾン層有害性カテゴリーができた（CLPには組込済み）

GHS Pictograms

ＧＨＳのピクトグラム

引火性ガス／可燃性ガス、引火性エアゾール
引火性液体、可燃性固体
自己反応性物質、自然発火性液体
自然発火性固体、自己発熱性物質
水反応可燃性／禁水性物質

Flammable gases
Flammable aerosols
Flammable liquids
Flammable solids
Self-reactive substances and mixtures
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which,
in contact with water,
emit flammable gases

火薬類、自己反応性物質
有機過酸化物

Explosives
Self-reactive substances
and mixtures
Organic peroxides

高圧ガス

Gases under pressure

急性毒性（高毒性）

Acute toxicity

呼吸器感作性、生殖細胞変異原性
発がん性、生殖毒性
特定標的臓器／全身毒性（単回暴露）
特定標的臓器／全身毒性（反復暴露）

Aspiration hazard
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity

急性毒性（低毒性）、皮膚刺激性
眼刺激性、皮膚感作性

Acute toxicity
Skin corrosion/irritation
Skin sensitization
Serious eye damage/eye irritation

水生環境有害性

Hazardous to the
aquatic environment

金属腐食性物質、皮膚腐食性
眼に対する重篤な損傷

Corrosive to metals
Skin corrosion/irritation
Serious eye damage/eye irritation

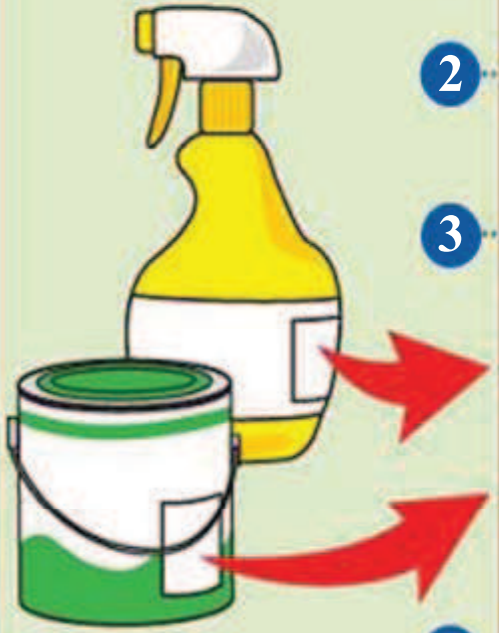
酸化性ガス類、酸化性液体
酸化性固体、有機過酸化物

Oxidizing gases
Oxidizing liquids
Oxidizing solids
Organic peroxides

Example of GHS Label

ＧＨＳラベルの例

Example of GHS Label



1 ●●●XXX

2 

3 **Danger**

4 **Causes severe skin burns and eye damage**
Extremely flammable liquid and vapour

5 **Do not get in eyes, on skin, or on clothing.**
Keep away from heat/open flames.
[Response]
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs:
Get medical advice/attention.
IF IN EYES: Rinse cautiously with water
for several minutes.

6 **xx Company, Phone Number xxx-xx-xxx**

1. **Chemicals identity**
   化学品に関する情報
2. **Pictogram**
   シンボルマーク
3. **Signal Word**
   注意喚起語
4. **Hazard Statements**
   危険有害性情報
5. **Precautionary Statements**
   注意書き
6. **Supplier identification**
   製造業者または供給者に
   冠する情報

GHS/CLP Hazard classification table

ＧＨＳとＣＬＰの危険有害性分類

Physical Hazards	Health Hazards
Explosives	Acute toxicity(oral,dermal,inhalation)
Flammable gases	Skin corrosion/irritation
Flammable aerosols	Serious eye damage/eye irritation
Oxidizing gases	Respiratory sensitization
Gases under pressure	Germ cell mutagenicity
Flammable liquids	Carcinogenicity
Flammable solids	Reproductive toxicity
Self-reactive substances and mixtures	Specific target organ toxicity - single exposure
Pyrophoric liquids	Specific target organ toxicity - repeated exposure
Pyrophoric solids	Aspiration hazard
Self-heating substances and mixtures	
Substances and mixtures which, in contact with water, emit flammable gases	
Oxidizing liquids	
Oxidizing solids	**Environmrntal Hazards**
Organic peroxides	Hazardous to the aquatic environment(acute,chronic toxicity)
Corrosive to metals	Hazardous to the ozone layer (Note)

(Note) incorporated into the 3rd edition (2009)

Hazard class difference; GHS vs CLP

ＧＨＳとＣＬＰの区分の違い

Hazards	Class						
Explosives	Unstable explosive	Division1.1	Division1.2	Division1.3	Division1.4	Division1.5	Division1.6
Flammable gases	Class1	Class2					
Flammable aerosols	Class1	Class2					
Oxidizing gases	Class1						
Gases under pressure	Compressed gas	Liquefied gas	Dissolved gas	Refrigerated liquefied gas			
Flammable liquids	Class1	Class2	Class3	Class4			
Flammable solids	Class1	Class2					
Self-reactive substances and mixtures	TypeA	TypeB	TypeC	TypeD	TypeE	TypeF	TypeG
Pyrophoric liquids	Class1						
Pyrophoric solids	Class1						
Self-heating substances and mixtures	Class1	Class2					
Substances and mixtures which, in contact with water,	Class1	Class2	Class3				
Oxidizing liquids	Class1	Class2	Class3				
Oxidizing solids	Class1	Class2	Class3				
Organic peroxides	TypeA	TypeB	TypeC	TypeD	TypeE	ﾀｲﾌﾟF	TypeG
Corrosive to metals	Class1						
Acute toxicity(oral,dermal,inhalation)	Class1	Class2	Class3	Class4	Class5		
Skin corrosion/irritation	Class1A	Class1B	Class1C	Class2	Class3		
Serious eye damage/eye irritation	Class1	Class2A	Class2B				
Respiratory sensitization	Class1						
Germ cell mutagenicity	Class1A	Class1B	Class2				
Carcinogenicity	Class1A	Class1B	Class2				
Reproductive toxicity	Class1A	Class1B	Class2	Effect on or via lactation			
Specific target organ toxicity - single exposure	Class1	Class2	Class3				
Specific target organ toxicity - repeated exposure	Class1	Class2					
Aspiration hazard	Class1	Class2					
Hazardous to the aquatic environment, acute toxicity	Class1	Class2	Class3				
Hazardous to the aquatic environment ,chronic toxicity	Class1	Class2	Class3	Class4			
Hazardous to the ozone layer	Class1						

CLP:Not adopted
区分不採用

CLP follows UN GHS

CLPはGHSの改訂に従う

- Recital 77 of CLP　CLP規則前文７７
  – “In particular the Commission should be empowered to adapt this Regulation to technical and scientific progress, including amendments made at UN level to the GHS …”
  特に、欧州委員会には国連GHSの改訂を含め、技術的・科学的進歩に適応させる権限が付与させなければならない
- Article 53(1) of CLP – “The Commission may adjust and adapt Articles … and Annexes I to VII to technical and scientific progress, including taking due account of the further development of the GHS …”
  CLP規則５３条の１-「欧州委員会は条項や・・・付属書I~VII]を国連GHSの開発の進展への細心の配慮を含め、技術的・科学的進歩に適合・適応させてもよい」

Introduction はじめに

UN GHS 国連GHS

CLP outline CLP概要

- **Transition from DSD/DPD to CLP** DSD/DPDからCLPへの移行
- **EU own Hazard Statements** 欧州独自の危険有害性情報
- **Classification & Harmonized classification**

  分類 & 調和された分類

Measures needed 必要な対応手段

Main features of CLP Reg.

CLP規則の主な特徴

- Applies the general principles of the UN GHS,
  原則として国連GHSを適用
- Keeps the scope as close as possible to the old EU system (Directives 67/548/EEC and 1999/45/EC),
  できる限り古い欧州方式に近づける
- Maintains the level of protection achieved in the EU by including EU “left-overs” that are not yet covered by the GHS, e.g. ozone depletion, EUH014, EUH066,
  GHSにまだ包含されていないEU “left-overs”を含めることで欧州が実現してきたレベルを維持
- Ensures consistency with transport, 輸送規則と整合
- Takes over the Annex I of Council Directive 67/548/EEC, 指令67/548/EEC付属書Iを引き継ぐ

Classification differences

分類の違い

DSD/DPD

E	Explosive	
F+	Extremely flammabl	
F	Highly flammabl	
O	Oxidizing	
T+	Highly toxic	
T	Toxic	
Xn	Harmful	
C	Corrosive	
Xi	Irritant	
Pollu tant	Pollutant	

CLP

Physical Hazards	Health Hazards
Explosives	Acute toxicity(oral,dermal,inhalation)
Flammable gases	Skin corrosion/irritation
Flammable aerosols	Serious eye damage/eye irritation
Oxidizing gases	Respiratory sensitization
Gases under pressure	Germ cell mutagenicity
Flammable liquids	Carcinogenicity
Flammable solids	Reproductive toxicity
Self-reactive substances and mixtures	Specific target organ toxicity - single exposure
Pyrophoric liquids	Specific target organ toxicity - repeated exposure
Pyrophoric solids	Aspiration hazard
Self-heating substances and mixtures	
Substances and mixtures which, in contact with water, emit flammable gases	
Oxidizing liquids	
Oxidizing solids	**Environmrntal Hazards**
Organic peroxides	Hazardous to the aquatic environment(acute,chronic toxicity)
Corrosive to metals	Hazardous to the ozone layer

From DSD/DPD to CLP timeline

DSD/DPDからCLPへの移行スケジュール

		Now 現在	1/12/2010- 2010年12月1日以降	1/6/2015- 2015年5月1日以降
Substances 物質	Label	DSD	CLP	CLP
	MSDS	DSD (+CLP:optional)	CLP and DSD	
Mixtures 混合物	Label	DPD	DPD	
	MSDS	DPD (+CLP:optional)	DPD (+CLP:optional)	

- Substances (Mixtures) with DSD(DPD) label, already placed on the market before 1/12/2010(1/6/2015) shall be relabeled within 2years
  期限までに市場にある物質・混合物への適用は２年間猶予

Transition
移行

- Traditional Dir.従来の法律
  - 67/548/EEC : DSD(Dangerous Substances Directive)
    危険な物質の分類・包装・表示に関する指令
  - 1999/45/EC : DPD(Dangerous Preparations Directive)
    危険な調剤の分類・包装・表示に関する指令
  - 2001/58/EC : SDS(Safety Data Sheet Directive)
    危険な物質と調剤のSDSに関する委員会指令
- New Reg.新たな法律
  - 1272/2008/EC : CLP(Classification, Labelling and Packaging) regulation 分類、表示と包装に関する規則
  - 1907/2006/EC (REACH) ANNEX II SDS (REQUIREMENTS FOR THE COMPILATION OF SAFETY DATA SHEETS)
    安全データシート編集に関する要求事項

Legal texts and guides

規則および主な参照文書

- REACH regulations REACH規則 ： (EC)No 1907/2006
- CLP regulations CLP規則 ： (EC)No 1272/2008 1355 pages
  - 1st ATP to CLP regulations CLP規則の改訂第一版 439 pages
- Guides ガイド
  - Introductory Guidance on the CLP Regulation ： CLP入門ガイド （also called as Module 1 とも言われる 117 pages）
  - Guidance on the Application of the CLP Criteria ： CLP適用ガイド （ also called as Module2 とも言われる 528 pages）
  - How to notify substances in the Classification and Labelling Inventory ： CLP届出ガイド 23 pages
  - Guidance on the preparation of dossiers for harmonised classification and labelling ： CLP文書ガイド 34 pages
- CLP Q&A 22 pages
- CLP FAQ 33 pages

Annexes to the CLP Regulation
CLP規則（1272/2008/EC）の付属書

- ANNEX I - CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES
  付属書I：有害性物質および混合物の分類ならびに表示
- ANNEX II - SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES
  付属書II：ある種の物質および混合物の表示ならびに包装についての特別規則
- ANNEX III - LIST OF HAZARD STATEMENTS, SUPPLEMENTAL HAZARD INFORMATION AND SUPPLEMENTAL LABEL ELEMENTS
  付属書III：ハザードステートメント、補足ハザード情報および補足ラベル情報
- ANNEX IV - LIST OF PRECAUTIONARY STATEMENTS
  付属書IV　　：予防ステートメントのリスト

Comprise 1319 pages of the entire 1355 pages of CLP

Annexes to the CLP Regulation

CLP規則（1272/2008/EC）の付属書 -Cont

- **ANNEX V - HAZARD PICTOGRAMS**
  付属書V：ハザード絵表示
- **ANNEX VI - HARMONISED CLASSIFICATION AND LABELLING FOR CERTAIN HAZARDOUS SUBSTANCE ***
  付属書VI：ある種の有害性物質に対する調和化された分類および表示
- **ANNEX VII - TRANSLATION TABLE FROM CLASSIFICATION UNDER DIRECTIVE 67/548/EEC TO CLASSIFICATION UNDER THIS REGULATION**
  付属書VII：指令67/548/EECに基づく分類からこの規則に基づく分類への変換表

* Annex VI: Comprise 1023 pages of the entire 1355 pages of CLP