



**Seminar on Tips from 2010 Registration –
Efficient Strategy for REACH registration in 2013/2018**

- Part III CLP: Review, lessons learnt and recommendations -

Tokyo, 26 October 2011

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Agenda



Introduction

Part I - REACH & CLP: new developments in the EU

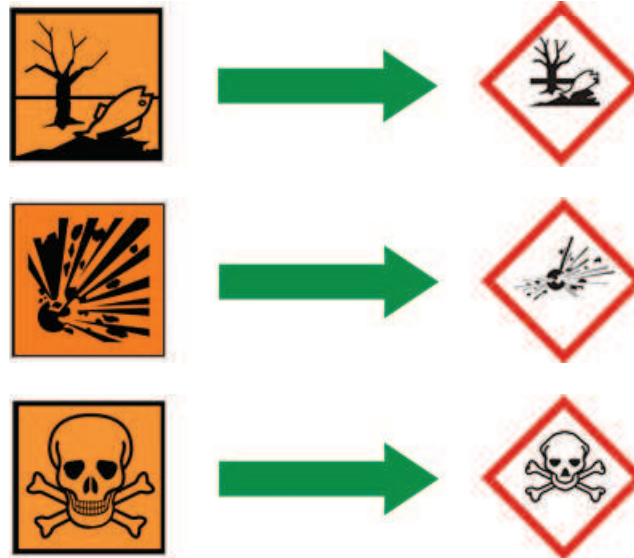
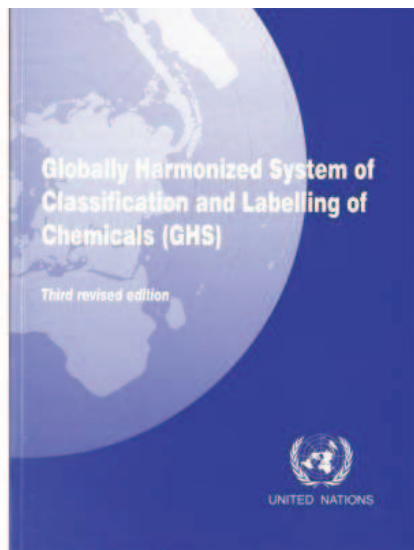
Part II - REACH: Review, lessons learnt and recommendations

Part III - CLP: Review, lessons learnt and recommendations

ANNEX

III Classification, Labelling and Packaging – Regulation EC (No) 1272/2008

- The Classification, Labelling and Packaging (CLP) Regulation EC (No) 1272/2008 replaced the Dangerous Substances Directive (DSD) 67/548/EEC and the Dangerous Preparations Directive (DPD) 1999/45/EC.
- It came into force on 20 January 2009 and applies across the European Union (stepwise approach).

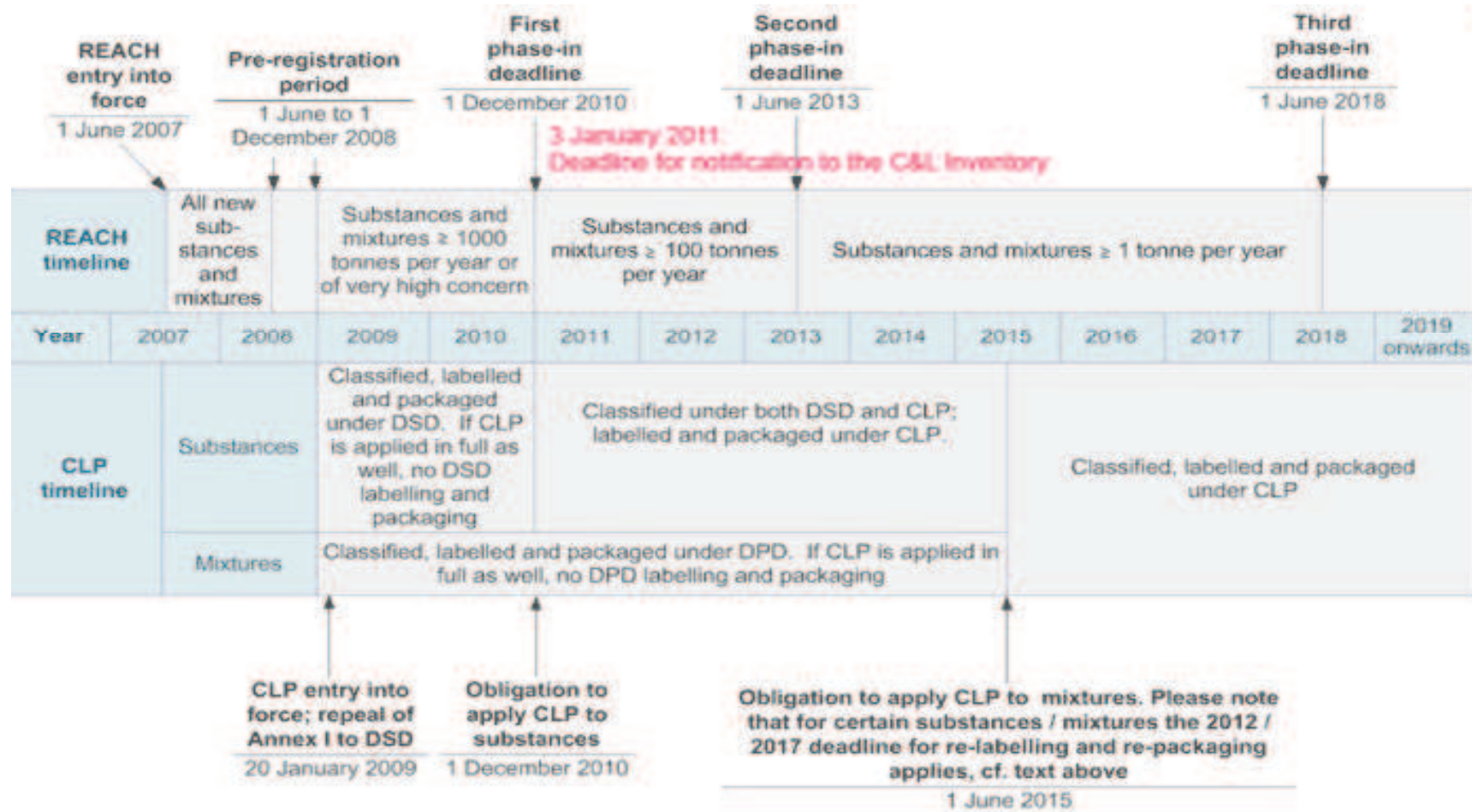


III Classification, Labelling and Packaging

Regulation EC (No) 1272/2008 (continued)

- CLP introduces several new aspects to the labelling and packaging of substances and mixtures.
- In general, the CLP label is based on the United Nations Globally Harmonized System of classification and labelling of chemicals (UN GHS), i.e. the new pictograms, signal word, hazard and precautionary statements.
- At the same time CLP retains some of the existing labelling concepts of DSD and DPD (e.g. small packaging exemptions).
- The CLP regulation sets out a phased transitional period during which the rules of both CLP and the previous legislation on classification, labelling and packaging, i.e. the DSD and DPD directives, are applicable in parallel.
- In relation to classification, labelling and packaging, CLP sets out different timelines for substances and mixtures.
- From entry into force, not all of the provisions of the CLP Regulation will be obligatory immediately. The transitional provisions contain different key dates that affect the classification and labelling of hazardous substances and mixtures:
 - ▶ 1 December 2010: obligation to apply CLP to substances
 - ▶ 1 June 2015: obligation to apply CLP to mixtures

III CLP Timeline (ECHA website)



III CLP – Obligations to notify to the C&L Inventory*)














- **If a substance is placed on the market and the substance is either**
 - ▶ **manufactured or imported** and subject to **registration** under the REACH Regulation; or
 - ▶ **manufacturee or imported** and **classified as hazardous, irrespective of the quantity**; or
 - ▶ **imported as part of a mixture** which contains the substance that is classified as hazardous and is present above the relevant concentration limit, which results in the classification of the mixture as hazardous according to the CLP Regulation; or
 - ▶ **imported as part of an article** wich containing substances which are subject to registration under Article 7 of the REACH Regulation.

*) ECHA website

III Example for submitted C+L to the inventory

Very high variation between different notifications

Previous 1-10 of 26 Next 10

Select	Classification Hazard category Hazard statement code	Labelling Pictogram	Signal word	Hazard statement code	Suppl. Hazard statement code	SCL M-Factor
<input type="radio"/>	Acute Tox. 4 Eye Irrit. 2 Aquatic Chronic 2 STOT SE 3	H302 H319 H411 H335	 	Wng	H302 H319 H335 H411	Expand
<input type="radio"/>	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Carc. 2 STOT SE 3	H302 H315 H318 H351 H335	 	Dgr	H302 H351 H335 H315 H318	Expand
<input type="radio"/>	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Carc. 2 STOT SE 3	H302 H315 H318 H351 H335	 	Dgr	H302 H351 H335 H315 H318	Expand
<input type="radio"/>	Acute Tox. 4 Eye Irrit. 2	H302 H319		Wng	H302 H319	Expand
<input type="radio"/>	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3	H302 H315 H318 H335	 	Dgr	H302 H315 H318 H335	Expand
<input type="radio"/>	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3	H302 H315 H318 H335	 	Dgr	H302 H315 H318 H335	Expand
<input type="radio"/>	Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 STOT SE 3	H302 H315 H318 H335	 	Dgr	H302 H315 H318 H335	Expand
<input type="radio"/>						Expand

III Notification to the C+L inventory

- Although the CLP deadline was 03 January 2011, legal obligations for further notifications are ongoing: obligation of every manufacturer/importer to notify hazardous (no tonnage threshold!) and also non-hazardous substances (> 1 t/a).
- Notification has to be done within 4 weeks after placing on European market.
- C&L notifications are submitted via the REACH-IT system (online, bulk upload, IUCLID).
- For substances already "registered" in accordance with Directive 67/548/EEC (NONS) by a company, CLP-notification is technically not possible in REACH-IT. Update of the IUCLID dossier required!
- Vast variety of notified classifications for the same substance (as of January 2011: 3.1 million notifications for 107,067 substances).
- Public version of the C&L inventory (1st release) is announced for end of 2011.
- Besides the CLH dossiers, procedure of different classifications per substance not clear.
- Change in C&L require also in update in the C&L inventory.
- Make sure that the harmonised C&L of the SIEF is also used in the C&L inventory.

III CLP Updates

- European CLP regulation is being updated every two years (Adaptations to the technical progress = ATP).
- 1st ATP (Regulation (EC) No 790/2009) updating Annex VI (legal classifications)
- 2nd ATP (Regulation (EC) No 286/2011) updating Annex VI and adapting the third revised edition of UN GHS from 2008.
 - ▶ Update of classification by 1 Dec. 2012 (substances)
 - ▶ Relevant also for mixtures (after 1 June 2015)

Update in C&L inventory required?

- ▶ New categories for skin and respiratory sensitisation
- ▶ New criteria for aquatic chronic toxicity
- ▶ New category: Dangerous to the ozone layer

- 3rd ATP expected for 2013 (also adapting UN revisions?)
- Fourth revised edition of UN GHS published 2011
http://live.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html

III Annex VI: Table 3.1:

List of harmonised C&L of hazardous substances

Table 3.1
List of harmonised classification and labelling of hazardous substances

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
001-001-00-9	hydrogen	215-605-7	1333-74-0	Harm. Gas 1 Press. Gas	H220	GHS02 GHS04 Dgr	H220			U
001-002-00-4	aluminium lithium hydride	240-877-9	16853-85-3	Water-react. 1	H260	GHS02 Dgr	H260			
001-003-00-X	sodium hydride	231-587-3	7646-69-7	Water-react. 1	H260	GHS02 Dgr	H260			
001-004-00-5	calcium hydride	232-189-2	7789-78-8	Water-react. 1	H260	GHS02 Dgr	H260			
003-001-00-4	lithium	231-102-5	7439-93-2	Water-react. 1 Skin Corr. 1B	H260 H314	GHS02 GHS05 Dgr	H260 H314	EUH014		
003-002-00-X	n-hexyllithium	404-953-0	21369-64-2	Water-react. 1 Pyr. Sol. 1 Skin Corr. 1A	H260 H250 H314	GHS02 GHS05 Dgr	H260 H250 H314	EUH014		
004-001-00-7	beryllium	231-150-7	7440-41-7	Carc. 1B Acute Tox. 2 * Acute Tox. 3 * STOT RE 1 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Skin Sens. 1	H350i H330 H301 H372 ** H319 H335 H315 H317	GHS06 GHS08 Dgr	H350i H330 H301 H372 ** H319 H335 H315 H317			

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Official Journal of the European Union

31.12.2008

III Annex VI: Table 3.2:

List of harmonised C&L of hazardous substances from Annex I to Directive 67/548/EEC

Table 3.2

The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
001-001-00-9	hydrogen	215-605-7	1333-74-0	F+; R12	F+ R: 12 S: (2-)9-16-33		
001-002-00-4	aluminium lithium hydride	240-877-9	16853-85-3	F; R15	F R: 15 S: (2-)7/8-24/25-43		
001-003-00-X	sodium hydride	231-587-3	7646-69-7	F; R15	F R: 15 S: (2-)7/8-24/25-43		
001-004-00-5	calcium hydride	232-189-2	7789-78-8	F; R15	F R: 15 S: (2-)7/8-24/25-43		
003-001-00-4	lithium	231-102-5	7439-93-2	F; R15 R14 C; R34	F; C R: 14/15-34 S: (1/2-)8-43-45		
003-002-00-X	n-hexyllithium	404-950-0	21369-64-2	F; R15-17 R14 C; R35	F; C R: 14/15-17-35 S: (1/2-)6-16-26-30-36/37/39-43-45		
004-001-00-7	beryllium	231-150-7	7440-41-7	Carc. Cat. 2; R49 T+; R26 T; R25-48/23 Xi; R36/37/38 R43	T+ R: 49-25-26-36/37/38-43-48/23 S: 53-45		E

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Official Journal of the European Union

L 353/923

III Comfortable search to Annex VI of the CLP regulation



<http://esis.jrc.ec.europa.eu/index.php?PGM=cla>

Search Annex VI to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Dangerous Substances.



Language

Index number

EC number

CAS number

Substance Name

Risk Phrases
To select more than one code, keep the CTRL key

- R2
- R3
- R4
- R5
- R6

Hazard Statement Codes
To select more than one code, keep the CTRL key

- EUH059
- H200
- H201
- H203
- H220

ATP

III GHS Converter

http://echa.europa.eu/clp/clp_help_en.asp

http://www.gischem.de/ghs/index.htm?client_locale=EN



The preselected category is a minimum requirement. This can be used if no data or other information is available as a basis for a new classification using the criteria in Annex I.

GHS class and category

Select one of the following indented lines based on your information (see note).

Acute toxicity (oral), Category 4 [Note 1](#)

Acute toxicity (oral), Category 3

Select one of the following indented lines based on your information (see note).

Acute toxicity (dermal), Category 4 [Note 1](#)

Acute toxicity (dermal), Category 3

Select one of the following indented lines based on your information (see note).

Acute toxicity (inhalation), Category 4 [Note 1](#)

Acute toxicity (inhalation), Category 3

These hazard classes and categories are clear-cut.

Flammable liquids, Category 3

Skin corrosion/irritation, Category 1B

Hazardous to the aquatic environment: Chronic hazard, Category 3

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H373: May cause damage ... (1)... through prolonged or repeated exposure ... (2)....

1: **Or state all organs affected, if known (see Safety Data Sheet)**

2: **Only state the route of exposure if it is conclusively proven that no other routes of exposure (e.g. inhalation, ingestion, skin contact) cause this hazard.**

H411: Toxic to aquatic life with long lasting effects.



III Harmonised Classification and Labelling (Annex VI CLP)

Standard processes

- Classification for a substance or mixture is mostly taken by its supplier (“self-classification”).
- In certain cases the decision on the classification of a substance is taken at Community level, which is then called “harmonised classification”.
- A harmonised classification (Annex VI) is legally binding and mandatory for the suppliers of the respective substance.

Who may prepare a proposal for the harmonised classification and labelling of a substance (CLH dossier)?

- Individual EU Member State Competent Authorities. These registry of intentions is published on the ECHA Website*.
- Manufacturers, importers and downstream users may ask for the classification and labelling of a substance to be harmonised across the European Union via MSCA.

*)http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_type=CLH&substance_state=current

III Harmonised Classification and Labelling^{*)} (continued)

Proposal for harmonised classification and labelling:

- where the substance is either
 - ▶ carcinogenic;
 - ▶ mutagenic;
 - ▶ toxic for reproduction; and/or
 - ▶ a respiratory sensitiser;
- when the substance is an active substance in a biocidal or plant protection products or
- when there is a need to harmonise a classification at EU level, supposed that justification can be provided demonstrating the need for such action.

Tool

- CLH dossier according to Annex XV of the REACH regulation:
 - ▶ Consist of a technical dossier (in IUCLID 5) and a CLH report attached to it.

III Experience made with CLP in 2010 and recommendations for the ongoing work

- Notification to the C+L inventory not always easy due to lack of data (often only old MSDS data available)
- Notification of imported raw products in mixtures very difficult for downstream users due to lack of data
- Change of submission tools and processes by ECHA in 2009-2011
- Annex VI entries are often not correct due to automatic translation from DSD classifications according to Annex VII CLP
- Change of harmonized classification (Annex VI) quite challenging (CLH dossier) and expensive (fees)
- C+L inventory not yet available and not very useful for downstream users due to high variance in notifications
- C+L inventory and Annex VI CLP are two independent lists
- Follow SIEF C&L as far as possible.
- Check C&L inventory for your own uses (undesired properties?).
- Be aware of upcoming changes.



ご静聴有難うございました。

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Annex: List of abbreviations

- CEFIC: European Chemical Industry Council
- CLH: Dossier with proposal for harmonised classification and labelling
- CLP: Classification, Labelling and Packaging
- CSR: Chemical Safety Report
- ECHA: European Chemicals Agency
- EHS: Environmental Health and Safety
- eSDS: extended Safety Data Sheet
- DNEL: Derived No-Effect Level
- DPD: Dangerous Preparations Directive
- DSD: Dangerous Substances Directive
- GPS: Global Product Strategy
- LoA: Letter of Access
- MSCA: Member States Competent Authorities
- NONS: Notification of New Substances Regulations; Substances notified under Directive 67/548/EEC
- OR: Only Representative
- PNEC: Predicted No-Effect Concentration
- QSAR: Quantitative Structure Activity Relationship
- RoHS: Restriction of Hazardous Substances Directive
- SCC: Scientific Consulting Company GmbH
- SIEF: Substances Information and Evaluation Forum
- SFF: SIEF Formation Facilitator
- SME: Small and medium sized enterprise
- SLOJ: SCC Liaison Office Japan
- SVHC: Substances of Very High Concern
- TCC: Technical Completeness Check
- UVCB: Substances of unknown variable composition, complex reaction products or biological materials
- VCI: German chemical industry association