

A world map with various regions highlighted in different colors: North America (green), South America (yellow), Europe (yellow), Africa (yellow), Asia (green), Australia (green), and New Zealand (purple). A large white text box with a purple border is centered over the map. At the bottom, there are three colored boxes: yellow for 'activities', green for 'preparation', and purple for 'Implementation'.

2.The EU CLP

*(Regulation EC No 1272/2008 on
classification, labelling and packaging of
substances and mixtures)*

activities

preparation

Implementation

1. Timing and history of the CLP

- Link and overlap with REACH
- Link with current EU system

2. Some important differences with the UN GHS

3. Implementation in practice

- Guidance
- Existing classifications and ATPs?



EMA

1. Timing and history



EU and the UN GHS (1)

- The EU confirmed its intention to contribute to the *global harmonisation of criteria for classification and labelling* through the incorporation of the agreed UN GHS criteria in community law
- *Supported by stakeholders* : industry, NGO's
- Existing Classification and Labelling systems in the EU:
 - Supply and use
 - Directive 67/548/EEC on Dangerous Substances
 - Directive 1999/45/EC on Dangerous Preparations
 - Different transport regulatory schemes
- Brave intensions expressed in 2005 :

« *The EU GHS system will supersede existing system over time and be implemented in parallel with REACH* »

EU and the UN GHS (2): Regulation on Classification, Labelling & Packaging (CLP)

A long procedure and a battled text, but in the end, it got published on the 31 December 2008 !!!

- Commission's internet consultation on proposal: Aug.'06

- Compromise

- Adoption

- Formal

- Published

Sept. 2008

January 20 2009

*Assume you have
"already implemented"
the necessary requirements?*

HOW COME YOU'RE SO QUIET
BACK THERE? AREN'T YOU
EXCITED TO SEE UNGHS

...YEAH...



But *No worry practical guidance is under development ...*

Reach Implementation Project (RIP) 3.6 develops GHS C&L standards/criteria under REACH

Basic guidance
to
Regulation
(EC) No 1272/2008
on
Classification,
Labelling and
Packaging
of substances and
mixtures

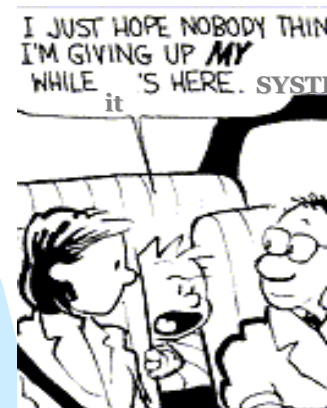


- Started in **October 2007**, finalization first half **2009 !!!!!**
- Develops :
 - **BASIC Guidance document (see your pack)**
 - **Specific Technical guidance on classification and labeling requirements for :**
 - Physico-chemical endpoints
 - Toxicological endpoints
 - Ecotoxicological endpoints

EU and the UN GHS (4):

Regulation on Classification, Labelling & Packaging (CLP)

- Applies **general principles** of UN-GHS
- Ensures **consistency** with EU transport regulation
- Uses **GHS building block approach** and a few other “optionalities” to *adapt the system to the EU needs:*



A GREAT WELCOME to HARMONISATION !!!

EU and the UN GHS (5):

Regulation on Classification, Labelling & Packaging (CLP)

BUT :

The Dilemma :

- stays *as close as possible to the UN GHS format* & terminology
- keeps the *scope as close as possible to the existing EU system*

The Practice :

“takes onboard basic features and procedures from DSD and DPD. Therefore, the CLP will be similar but not identical to... how the GHS is implemented outside the EU.”

Although ... HARMONISATION à la carte ??

EU and the UN GHS (6): Regulation on Classification, Labelling & Packaging (CLP)

Main aims :

1. Enable a *judgment on a substance or mixture* (preparation) with respect to its *hazardous properties*
2. Provide a hazardous chemical with *pertinent hazard labelling and information on safety measures*

The CLP regulation should :

- Ensure a *high level of protection* of human health and the environment
- *free movement of chemical substances, mixtures ...* , while enhancing competitiveness and innovation

EU and the UN GHS (7)

Regulation on Classification, Labelling & Packaging (CLP)

How does it look ?

MAIN LEGAL TEXT

TITLE I - General Issues

TITLE II – Hazard Classification

- ✓ Chapter 1 Identification and Examination of Information
- ✓ Chapter 2 Evaluation of Hazard Information and Decision on Classification

TITLE III – Hazard Communication in Form of Labelling

- Chapter 1 Content of the Label
- Chapter 2 Application of Labels

TITLE IV – Packaging

TITLE V – Harmonisation of C&L of Substances and the C&L Inventory

- ✓ Chapter 1 Establishing Harmonised Classification and Labelling of Substances
- ✓ Chapter 2 Classification and Labelling Inventory

TITLE VI – Competent Authorities and Enforcement

TITLE VII – Common and Final Provisions

EU and the UN GHS (8)

Regulation on Classification, Labelling & Packaging (CLP)

How does it look ? ANNEXES of the LEGAL TEXT

Annexes on technical details

- ✓ **Annex I:** **Classification and labelling requirements for hazardous substances and mixtures**
- ✓ **Annex II:** **Special rules for labelling and packaging**
- ✓ **Annex III:** **List of Hazard Statements (ex R list)**
- ✓ **Annex IV:** **List of Precautionary Statements (ex S list)**
- ✓ **Annex V:** **Pictograms**
- ✓ **Annex VI:** **Harmonised List of Hazardous Substances**
- ✓ **Annex VII:** **Translation Table for classification**

EU and the UN GHS (9)

Regulation on Classification, Labelling & Packaging (CLP)

Timing : GENERIC PRINCIPLES

January 20, 2009:

Entry into force CLP, repeal Annex I DSD

December 1, 2010:

Obligation to apply CLP to substances

June 1, 2015:

Obligation to apply CLP to mixtures

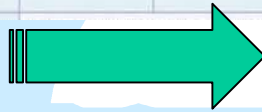


EU and the UN GHS (10)

Regulation on Classification, Labelling & Packaging (CLP)

Until December 1, 2010:

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards
------	------	------	------	------	------	------	------	------	------	------	------	------	--------------



Substances

MUST be Classified, labelled
packaged under DSD

MAY: Classified, labelled
packaged under CLP.

No DSD label/package

Mixtures

MUST be: Classified, labelled
packaged under DPD

MAY: Classified, labelled
packaged under CLP.

No DPD label/package



EU and the UN GHS (11)

Regulation on Classification, Labelling & Packaging (CLP)

FROM 1 December 2010 (CLP replaces DSD substances)

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards



Substances

MUST be Classified in accordance with DSD and CLP, labelled and packaged under CLP

*Note: **substances** already classified, labelled and packaged according to DSD and placed on the market <December 1 2010 will have to be re-packaged and re-labelled by 1 December 2012*

Mixtures

MUST be Classified, labelled packaged under **DPD**

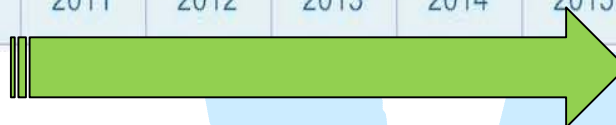
MAY be Classified, labelled packaged under **CLP**.
No DPD label/package

EU and the UN GHS (12)

Regulation on Classification, Labelling & Packaging (CLP)

THE LATEST, 1 December 2015 (CLP replaces DPD mixtures)

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards



Substances

MUST be classified, labelled & packaged under CLP

Mixtures

MUST be classified, labelled & packaged under CLP

*Note: **mixtures** already classified, labelled and packaged according to DPD and placed on the market < June 1 2015 will have to be re-packaged and re-labelled by 1 June 2017*

I HATE BEING GOOD.



ENM

- Link and overlap with REACH

Links CLP and REACH (1)

Obligation to **classify in the EU** :

- ✓ The CLP- and
- ✓ REACH Regulations:

CLP Regulation (CLP Article 4(1)):

If you are a M/I or DU of chemical substances or mixtures to be placed on the market, *you should classify these substances or mixtures before placing them on the market*, independent from any tonnage manufactured, imported or placed on the market

REACH (CLP Article 4(2)):

If you are a M/I, *you should also classify substances which you do not place on the market* if they are subject to registration or notification in line with Articles 6, 9, 17 or 18 of REACH (incl. on-site isolated or transported intermediates).

Links CLP and REACH (2)

Scope

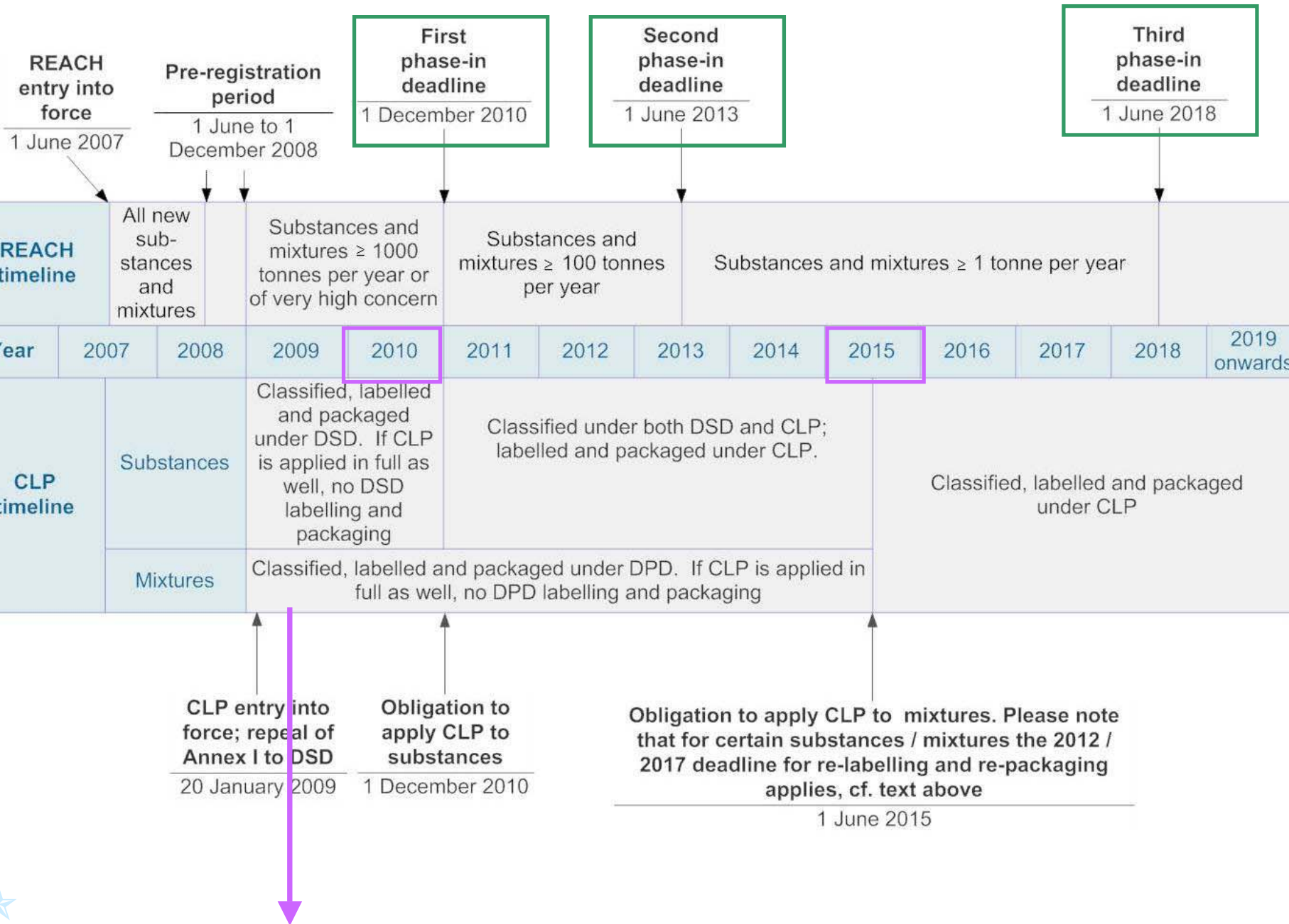
REACH	EU-CLP
R, E, A, Ch	Classification, Labelling, SDS
Risk	Hazard
Substances produced / imported	Substances/Mixtures
Hazardous and non-Hazardous	Hazardous
≥1 tonne/year/producer or importer	Any volumes
Harmonised classifications	Self classification
European Union	EU (but comparable at WW level)
Workplace and Supply	Workplace, Supply and Transport

Links CLP and REACH (3)

REACH does **NOT include CRITERIA** for classification and labelling

- it refers to:
 - ✓ Substance classification ⇒ Directive 67/548/EEC
 - ✓ Preparation classification ⇒ Directive 1999/45/EC
 - ✓ Safety Data Sheets ⇒ REACH Annex II
- but has links to **classification and labelling**
 - ✓ Registration
 - ✓ Information in the supply chain
 - ✓ **C&L Inventory - Title XI; moved to CLP Title V**

Links CLP and REACH (4): Summary



Links CLP and REACH (5)

REACH

Substances registered before 1 December 2010 shall be registered with a classification according to DSD. However, the registration may also contain the classification according to CLP, as far as available

Substances registered between 1 December 2010 and 1 June 2015 shall be registered with a classification according to both DSD and CLP

Substances registered after 1 June 2015 shall be registered with a classification according to CLP alone

Links CLP and REACH (6)

STEP 1 :

Classifications for substances placed on the market and intermediates should be submitted to the REACH IT system before Dec 1.

STEP 2 :

They will be included in a classification and labelling inventory established at the Agency (*CLP Article 42*)

In case of ARTICLES :

Producers must provide information on substances of high concern contained in articles to the Agency if they are present in those articles above 1 tonne per producer or importer per year and contained in the articles in concentrations above 0.1% (w/w) (*REACH Article 7(2)*).

Links CLP and REACH (7)

- ECHA is central to the implementation of both REACH and CLP, to ensure consistency across the EU
- Tasks:
 - Provide industry/Member State competent authorities with technical and scientific guidance on the CLP
 - Provide support to the (national) helpdesks set up under CLP
 - Establish and maintain a C&L inventory in the form of a database and receive notifications to the inventory
 - Receive proposals for the harmonised classification of a substance from Member State competent authorities and suppliers and submit an opinion on such proposals to the Commission
 - Receive, evaluate and decide upon the acceptability of requests to use alternative chemical names
 - Prepare and submit to the Commission draft exemptions from the labelling and packaging requirements

Links CLP and REACH (8)

HARMONISED CLASSIFICATION :

An aim of the SIEF is to agree the classification and labelling for the same substance

IF NOT :

- Different registrants will register different Classifications
- ECHA/MS have the right to launch an harmonisation procedure

So conclusively :

ensure harmonised classifications for as far as possible.

EMA

- Similarities and differences with current EU system

Similarities with EU 'classifical' C&L system (1)

- CLP is aimed at workers and consumers, and covers the supply and use of chemicals
- It does not cover the transport of chemicals, although testing for physical hazards is largely inspired from the UN Recommendations on the Transport of Dangerous Goods

(transport is covered by the Framework Directive 2008/68/EC implementing the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN))



Similarities with EU 'classical' C&L system (2)

- Overall scope of classification under CLP is comparable with DSD/DPD
- CLP does not include categories not part of current EU system (acute toxicity category 5, acute aquatic toxicity categories 2, 3)
- Elements part of DSD/DPD not yet included in the UN GHS are in the CLP (e.g. hazardous to the ozone layer, coded differently)

Differences with EU 'classical' C&L system (1)

- Differences in key terminology:
 - Mixtures instead of preparation: *'means a mixture or solution composed of two or more substances'*
 - Hazardous instead of dangerous : *'a substance or mixture fulfilling the criteria relating to physical, health or environmental hazards, laid down in CLP Annex I is hazardous'*
 - Hazard class/hazard category: *'The nature/severity of a physical, health or environmental hazard'*
- New terms: pictogram, signal word, hazard statement, precautionary statement, supplier

Differences with EU 'classical' C&L system (2)

- The number of hazard classes has increased, in particular for physical hazards (from 5 to 16!!)
- Classification of mixtures under CLP:
 - as in the DPD, available data obtained from testing the mixture as a whole should primarily be exploited
 - if cannot be done, further approaches that may be applied differ partly from those under DPD (bridging principles for some health and environmental hazards, using data on similar tested mixtures, calculations formulae differ from those used under DPD)
- Wording on application of expert judgement and weight of evidence are more explicit in the CLP legal text when compared to DSD

Differences with EU 'classical' C&L system (3)

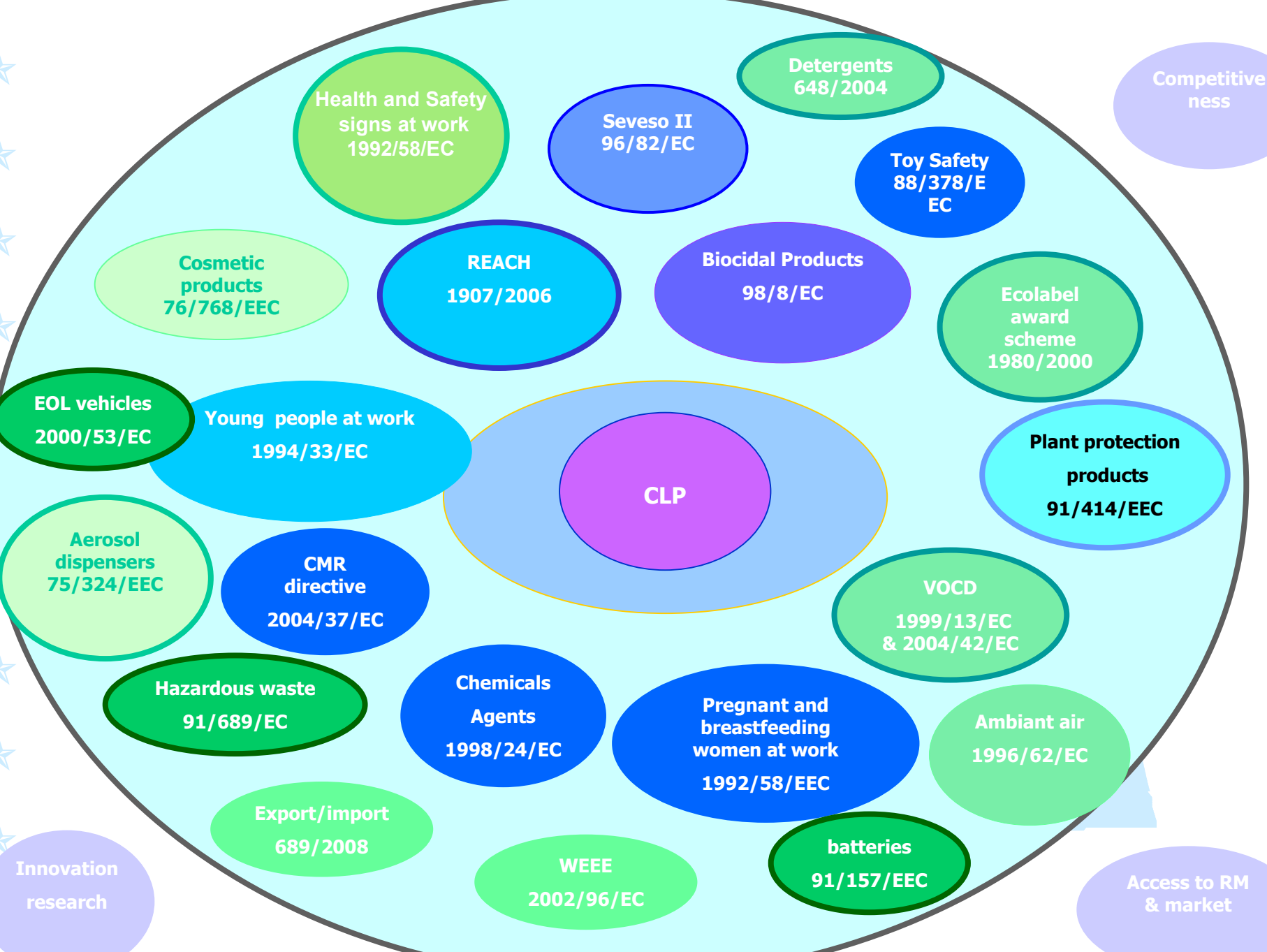
- Harmonised classifications:

CLP also includes provisions for *harmonised classification of substances* to be applied directly. Proposals for such harmonised classification may be submitted either by Member State Competent Authorities or **by manufacturers, importers, or downstream users themselves**

- *CMR substances and respiratory sensitisers category 1*
- *other properties if justification is provided*

Link with other legislations

- Many provisions of CLP are also closely linked to provisions under other community legislations
- « Downstream legislation »: obligations in Community legislation referring to classification and labelling
 - More than 20 pieces of EU downstream legislation refer to C&L
 - Careful analysis of possible effects by Commission Services
 - 'study demonstrates that effects are mostly minimal or can be minimised through appropriate consequential changes »
- Provisions under those pieces of legislation may be triggered by the classification of your substance/mixture



Competitiveness

Detergents
648/2004

Seveso II
96/82/EC

Toy Safety
88/378/E
EC

Health and Safety
signs at work
1992/58/EC

REACH
1907/2006

Biocidal Products
98/8/EC

Ecolabel
award
scheme
1980/2000

Cosmetic
products
76/768/EEC

Young people at work
1994/33/EC

CLP

Plant protection
products
91/414/EEC

EOL vehicles
2000/53/EC

Aerosol
dispensers
75/324/EEC

CMR
directive
2004/37/EC

VOC
1999/13/EC
& 2004/42/EC

Hazardous waste
91/689/EC

Chemicals
Agents
1998/24/EC

Pregnant and
breastfeeding
women at work
1992/58/EEC

Ambiant air
1996/62/EC

Export/import
689/2008

WEEE
2002/96/EC

batteries
91/157/EEC

Innovation
research

Access to RM
& market



2. Some differences between the EU and UN
GHS

GHS / EU

- similar framework - different elements

The GHS is **different** to the current EU system:

- It sets criteria for both transport and supply and use
- It defines further hazard classes and categories
- It uses partly other criteria and other cut-offs
- It uses a different approach for mixtures
- It changes some labelling elements

GHS / EU

- similar framework - different elements

UN GHS categories not included in the CLP

Table A4.1: Hazard categories included in the UN GHS but not in CLP		
Hazard classifications	UN GHS hazard categories not in CLP	Comments
Flammable liquids	Cat. 4	Flammable liquids with a flash point $\leq 93^{\circ}\text{C}$ are used for the classification of flammable aerosols
Acute toxicity	Cat. 5	
Skin corrosion/ irritation	Cat. 3	Mild irritant
Serious eye damage/ eye irritation	Cat. 2B	CLP Cat. 2 is equivalent to Cat. 2A of UN GHS
Aspiration hazard	Cat. 2	
Hazardous to the aquatic environment	Acute Cat. 2 and Cat. 3	

GHS / EU

- similar framework - different elements

Additional labelling and packaging rules:

CLP includes special rules not included in the UN GHS:

- for substances and mixtures in small packaging (*CLP Article 29*)
- on supplemental hazard information (*part I of Annex II to CLP*)
- on supplemental label elements for certain mixtures (*part 2 of Annex II to CLP*) and for the provision of child-resistant fastenings and/or tactile warnings (*part 3 of Annex II to CLP*)
- it includes rules for the situation when a substance is both covered by CLP and by transport legislation.



3. Implementation in practice

ENM

- Guidance

Guidance (1)

- REACH Implementation Project 3.6 (RIP 3.6) develops guidance on application of the proposed Regulation under development
- Four working groups: general issues, physical, health and environmental hazards drafting specific guidance (module 2)
- In addition, a short and industry-oriented guidance on basic features and procedures was prepared by RPA (module 1)

Guidance (2)

Basic guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures



Table 2.2: Obligations of a manufacturer or importer (cont.)

Obligations under CLP		Key Sections
8	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance (<i>part 3 of Annex VI to CLP</i>) you should submit a proposal to the competent authority in one of the Member States in which the substance is placed on the market (<i>CLP Article 37(6)</i>)	22
9	You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture. This information should be kept together with the information required in Article 36 of REACH (<i>CLP Article 49</i>)	21

Note: Importers and downstream users placing mixtures on the market should be prepared to provide certain information relating to mixtures to those Member State bodies which are responsible for receiving such information in order to formulate preventative and curative measures, in particular in the event of emergency health response (*CLP Article 45*).

Guidance (3)

- Addressed to suppliers (M/I, DU including formulators, distributors including retailers and producers/importers of certain specific articles*)
- Easily digestible text to allow quick and effective orientation on the obligations under CLP
- Highlight of relevant obligations and links to REACH, Directive 1998/8/EC on biocidal products, Directive 1991/414/EEC on plant production products

*: producers/importers of an explosive article as described in section 2.1 or where REACH Art 7,9 provide for registration/notification of a substance contained in an article

Guidance (4)

Descriptions		Your role under CLP
3	A natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities	Downstream User ⁽²⁾ (including formulator / re-importer)
4	A natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties	Distributor (including retailer)
5	A natural or legal person who makes or assembles an article within the Community; where an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition	Producer of articles ⁽³⁾
Notes: (1) In everyday language the term “manufacturer” can cover both the (natural/legal) person making substances and the (natural/legal) person making mixtures (formulator). In contrast to this everyday language, the term “manufacturer” in REACH and CLP only covers the person making substances. The formulator is a “downstream user” under REACH and CLP. (2) A distributor or consumer is not a downstream user. (3) As a producer or importer of an article you are only affected by CLP if you produce or import an explosive article as described in section 2.1 of Annex I to CLP or where REACH Article 7 or 9 provide for registration or notification of a substance contained in an article.		

Guidance (5)

- Step 1: is your substance on the harmonised classification list?
 - If no, go to step 2
 - If yes, classify accordingly or justify new classification based on new evidence and submit Annex XV (REACH)
- Step 2: you have data and self classification under old system
 - If yes: use translation tables
 - If no: go to step 3
- Step 3: conduct base testing under REACH and gather additional relevant information and classify accordingly to Annex I

QMA

- Existing classifications and ATPs

Existing classifications and ATPs

- CLP takes over current Annex I of DSD : Annex VI of CLP: translation Annex I DSD in 'CLP' classifications
- Annex VII of CLP: translation tables to translate existing* classifications to CLP classifications

EU R-Phrase	GHS code	GHS hazard
R42	H334	Respiratory Sensitiser
R43	H317	Skin Sensitiser
Carc.Cat.2; R45	H350	Carcinogen Cat. 1B
Repr.Cat.2; R60	H360	Reproductive toxicant Cat. 1 B ("May damage fertility")
Repr.Cat.2; R61	H360	("May damage unborn child")

*: substance classified before December 1 2010, mixture classified before June 1 2015

Existing classifications and ATPs

- 30st and 31th ATP: (amending Annex I to Directive 67/548/EEC):
 - Since these classifications were adopted after a first reading agreement was reached on the text of the CLP, they could not be included in the text (Annex VI) of the CLP Regulation
 - The Commission has prepared a proposal for a first ATP to the CLP Regulation with a view to transferring the harmonised classifications contained in the 30th and 31st ATPs into Annex VI to the CLP Regulation. This ATP will take the form of a Regulation and therefore be directly applicable throughout the EU

Existing classifications and ATPs

- « Annex I is deleted by Article 55(11) of EC Regulation 1272/2008 as of its entry into force (20 January 2009)
 - meaning that the 30th and 31st ATPs, which amend Annex I, are also no longer in force
 - the gap created by this deletion should be filled once the 1st ATP of the CLP Regulation enters into force - (middle of 2009)
 - In the meantime, companies should be strongly encouraged to apply the harmonised classifications contained in the 30th and 31st ATPs for the substances not yet listed in Annex VI of the CLP Regulation »...based on data!!!

EM

Finally...



European Commission

Conference on EU and world-wide rules for classification, labelling and packaging of chemicals

EU Regulation on Classification, Labelling and Packaging (CLP) of substances and mixtures
based on the UN Globally Harmonised System (GHS)

17 June 2009, Brussels

The event is planned to be webstreamed

