

EU chemical regulation - GHS and REACH

Jytte Syska, 3E Company

EU and Europe in 2009



- 27 member state countries
- 23 languages
- EEA: Norway, Iceland, Lichtenstein
- Switzerland
- EU Legal instruments:
 - Regulations
 - Directives
 - Decisions



English

European Chemicals Agency

Legal notice | Contact | Links

- HOME
- PRE-REGISTRATION
- REACH
- CONSULTATIONS
- ECHA CHEM
- REACH-IT
- CLASSIFICATION
- PRESS AND EVENTS
- ABOUT ECHA
- PUBLICATIONS
- WORKING WITH US
- APPEALS

European Chemicals Agency (ECHA)

The Agency, located in Helsinki, Finland will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing.

During the first 12 months the Agency is building up its organisation and recruiting personnel to be ready to accept registrations from 1 June 2008.

[More](#)

How to discover the ECHA website

The ECHA website is a single point of entry for all information on REACH. It provides access to technical guidance, frequently asked questions (FAQs), software tools and helpdesks. Here you will also find the latest updates on guidance, tools, data on chemicals and the Regulation.

[More](#)



NEWS

- First coordinated REACH enforcement project started, 30/04/2009
- Getting started in SIEFs - top tips published, 24/04/2009
- ECHA launches open call for tender for risk communication guidance, 23/04/2009

EU CLP



- CLP = Classification, Labelling & Packaging
- CLP is the name used for the EU implementation of GHS
- GHS was adopted in the EU on December 16th, 2008 and came into force January 5th, 2009
- Implemented (transposed) via a Regulation
 - In force in each Member State immediately and only for the enforcement part, national laws will be required – like for REACH.
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures: CLP
 - Applies to
 - Companies placing chemicals on the market and
 - Other companies with registration requirements under REACH

EU CLP - summary



- Require
 - manufacturers, importers and downstream users to classify chemicals;
 - suppliers of chemicals to label and package the products before placing them on the EU market;
 - manufacturers and importers to notify the Chemical Agency of the classification and labeling of substances;
- Establish (keep) a list of substances with mandatory (harmonized) classification and labeling; and
- Establish the Classification and Labeling Inventory

EU Classification – CLP & “old”



Regulates classification, labeling and packaging

- Replaces the Substance Directive (67/548/EEC) and the Preparations Directive (1999/45/EC)
 - Both directives will be fully replaced by June 1, 2015
- Substances classified under the Substance Directive must be classified using
 - List of mandatory (harmonized) classification.
 - has been transferred from Annex 1 in 67/548/EEC to Annex 6 table 3.2 in 1272/2008 (CLP)
 - Self classification (provisional classification): Article 6 of 67/548/EEC
 - Required until June 2015 in conjunction with the CLP
- Products classified under the Preparations Directive must be classified according to this legislation
 - CLP classification may be initiated now

CLP Classification



- Title II – Hazard Classification
 - Applies to substances Dec 1, 2010 and to mixtures Jun 1, 2015
 - But note special requirements for substance classification in the SDS
- The EU CLP Regulation does not implement the UN GHS system in its entirety.
 - The GHS building block approach allows that only the appropriate hazard classes and categories are chosen.
- The following GHS categories are not included in the EU CLP Regulation:
 - Flammable liquids cat. 4
 - Skin corrosion/irritation cat. 3
 - Acute toxicity cat 5
 - Aspiration hazards cat 2
 - Acute aquatic toxicity cat. 2 and cat. 3
- These hazard categories are not covered under the current EU system and are not needed for consistency with the transport legislation.
- The additional EU hazard class “Hazardous to the ozone layer” is kept

CLP - Classification (cont'd)



- Concept of mandatory (harmonised) classification is kept:
 - The old “Annex 1” has been converted into Annex VI Table 3.1
 - More substances with harmonised C&L will be added
 - respiratory sensitization category 1, category 1A, 1B and 2 carcinogens, germ cell mutagens, and reprotoxic substances, substances in plant protection products and in biocides, others
 - Substances on Annex VI Table 3.1 must be assessed for other hazard classes and differentiations (Art 4 item 3)
 - Some substances on Table 3.1 has an “*” indicating minimum classification for a category
- Other substances must be classified according to Title II (Hazard Classification)
- Use conversion table for substances and mixtures to help ease transition
 - Annex VII to the EU CLP Regulation
 - Only for substances and mixtures that have been classified under the old system

EU CLP – C & L Inventory



1272/2008

- Takes over Title XI from the REACH Regulation (the Classification and Labeling Inventory)
- Title V, chapter 2 C&L inventory
 - Applies to substances subject to registration under REACH and to substances placed on the market (as pure substances or in a mixture)
- Notification to ECHA
 - From December 1, 2010 and then latest 1 month after placing on the market
 - Each notifier shall only notify a certain substance once
 - Substances that have been registered under REACH by that notifier need not be notified
- Substance information (C&L, etc) will be published in a database by ECHA
 - Certain information will be public available (coordinated with Art 119(1) of REACH)

Hazard Communication - Labels



- Label requirements follow the UN purple book
- “Supplemental Information” (Art 25 and 32)
 - Annex II, 1.1 and 1.2 phrases, e.g EUH14 “Reacts violently with water” or EUH201A “Contains lead”
 - Biocides (91/414/EEC – special phrase
 - If substance on Annex VI with supplemental hazard statements (e.g. acetone with EUH066 “Repeated exposure may cause skin dryness or cracking”)
 - If classified for ozone depletion: signal word, H- and P statements
 - Label information required by other regulations
 - Other relevant information provided by the supplier
- Pure substances must be labelled according to 1272/2008 latest by Dec 1, 2010
- Mixtures must be labelled according to 1272/2008 latest by Jun 1, 2015
- Existing products have 2 more years to get re-labelled

Hazard Communication - SDSs



- Safety Data Sheets are still regulated by REACH
- SDS for pure substances
 - Shall include the classification according to 1272/2008 from Dec 1, 2010
 - Until Jun 1, 2015 Sec 2 and Sec 3 shall show both old and new classification
- SDS for mixtures
 - Shall show the classification according to 1272/2008 from Jun 1, 2015 (Sec 2 and 3)
 - If classified under 1272/2008 before Jun 2015:
 - Sec 2 must show product classification from both systems (1272/2008 and 1999/45/EC)
 - Sec 3 must show substance classification from both systems (1272/2008 and 67/548/EEC)
- CLP classification (sec 2 and 3) includes:
 - Hazard statements, Hazard classes and categories
- Section 15 must show the “old” label (67/548/EEC and 1999/45/EC) as long as used and the CLP (1272/2008) label when used

Thank you for your attention!

Jytte Syska

3E Company Europe

Email: jsyska@3ecompany.com

Phone: +45 70 22 81 70

Cell: +45 21 64 25 26