## EU Chemicals Legislation

### Legislation changes

<table>
<thead>
<tr>
<th>Substances</th>
<th>Directives, &gt; 60</th>
<th>Regulation 1907/2006</th>
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**Aim:** To gather all relevant information on the intrinsic properties, the risks for health and environment, of all substances on the EU market.

- (obligatory registration for production >1 tonne/yr by 2018)
- (special care for Substances of Very High Concern (SVHC), like CMR)
- (industry responsible for risk assessment/management/communication)

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### Legislation changes (PC articles)

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**Plant Protection Products**

<table>
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<tr>
<th>Directives</th>
<th>Regulation 1107/2009</th>
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<tbody>
<tr>
<td>Directive 91/414</td>
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<tr>
<td>Directive 76/768</td>
<td>Regulation 1233/2009</td>
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**Biocidal Products**

<table>
<thead>
<tr>
<th>Directives</th>
<th>Regulation 2011</th>
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<td>Directive 96/8</td>
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**Aim:** To align previous EU legislation on classification, labelling and packaging of chemicals with the UN system of GHS, the Globally Harmonised System of classification and labelling of chemicals. (worldwide identical classification of chemicals)

(all substances/2015) and mixtures (Jun-2015) have to be reclassified (introduction of new hazard classification terminology and rules)

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### EAPCCT working group

**European Association of Poisons Centres and Clinical Toxicologists**

**WG on Poisons Centres Activities / European Regulatory Issues**

Dr Herbert Desel, chair (Göttingen, EAPCCT Board)

Dr Hugo Kupferschmidt (Zürich, EAPCCT past-President)

Poisons Centres representatives from:

- Netherlands
- Italy
- Norway
- Czech Republic
- Germany
- Ireland
- Sweden
- Romania
- Belgium
- Switzerland
- Denmark
- Serbia
- France
- UK
- Estonia
- Spain

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**EAPCCT Notification Directive Information Preparation**

Art Pieter Bre 7

**Article 17**

1999/45

**Article 13**

Colipa

**Article 23**

ECHA
European Association of Poisons Centres and Clinical Toxicologists

WG on Poisons Centres Activities / European Regulatory Issues

Major regulatory issues:
- Harmonisation of Product Information: CLP 45(4) review by COM (Klaus Berend / Karola Grodzki)
  lead: Ronald de Groot (NL)
- Cosmetic Products Notification Portal (CPNP) working group (Art. 13) (Aurelien Perez)
  lead: Herbert Desel (DE)
Ad hoc WG on IT issues  lead: Pieter Brekelmans (NL)
Ad hoc WG on Categorisation lead: Andreas Stürer (DE)
Ad hoc WG on Frame Formulations  lead: Martine Mostin (BE)

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CLP Regulation

Art. 45 Bodies responsible for receiving information relating to health (first draft by the European Commission in July 2007)

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in case of emergency.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out the tasks for which they are responsible.

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Report conclusions

Harmonisation of product notification in the EU

Step 1 – Reach consensus on required product information
=> EAPCCT guideline (1989!) is still a good compromise

Step 2 – Establish common (electronic) format
=> Required information as structured data (XML)

Step 3 – Implementation in EU legislation
=> Preferably into the CLP Regulation

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CLP regulation

EC No 1272/2008, article 45, paragraph 4

By 20 January 2012 the Commission shall carry out a review to assess the possibility of harmonising the information referred to in paragraph 1, including establishing a format for the submission of information by importers and downstream users to appointed bodies. On the basis of this review, and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission may adopt a Regulation adding an Annex to this Regulation.

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European Association of Poisons Centres and Clinical Toxicologists

By DG Enterprise & Industry
Lead by Klaus Berend / Karola Grodzki (Uta Jensen-Korte)
- Sept 18th 2009 Introductory meeting
- March 17th 2010 1st meeting of COM and PIC representatives
- May 28th 2010 2nd meeting of COM, PIC and some GA representatives
- Aug 2010 3rd meeting with PIC representatives
- Sept 2010 endorsed draft of EAPCCT 2010 guidelines
- Nov 24th 2010 Workshop with stakeholder representatives

Brussels, 24 november 2010
Workshop on the Harmonisation of Information to Poisons Centres

Klaus Berend Karola Grodzki

The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible

(CLPRegulation (EC) No 1272/2008, article 45/3)

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Contents of guideline
Update of the 1989 guideline:

1. COMPANY INFORMATION
   - Company placing the mixture on the market
   - Company submitting the mixture information
   - Contact Point(s) in case of emergency

2. PACKAGING
   - CLP Category

3. IDENTIFICATION OF THE MIXTURE
   - Mixture identifiers
   - Product Identification Element

4. COMPOSITION
   - Substances in the mixture
   - Substance concentrations
   - Reformulation

5. CATEGORISATION
   - Product Category
   - Consumer / Professional use

6. CLASSIFICATION
   - Classification
   - Label elements

7. PHYSICAL/ CHEMICAL CHARACTERISTICS
   - Physical state
   - pH
   - Total reserve acidity/alkalinity

8. OTHER INFORMATION
   - Contact Point(s)

Endorsed by the EAPCCT board in sep 2010

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The EAPCCT guidelines 2010

Product (information) identification

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Product identification element

Product Name
Product Formula

Product Label
Product Information

Product Identification Element

Product Name

Product Formula

Product Name

Product Formula

Brussels, 24 November 2010
Axel Hahn

European Association of Poisons Centres and Clinical Toxicologists

Product versioning

Product Name
Product Label

Product Information

Product Name

Product Formula

Product Name

Product Formula

Brussels, 24 November 2010
Herbert Desel

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Product categorisation

Use of a product categorisation system
- To categorise product of exposure in the case recording
- During processing/storage of incoming product information
- Retrieval of comparable products if right product is missing
- Retrieval of case series (scientific evaluation/reporting)
- Grouping of cases for annual reports

- Much experience in Germany: harmonisation at national level (TDI)
- Extrapolate internationally:
  - to compare exposure data of products between EU PCs
  - to combine exposure data of EU PCs in an annual report
  - to analyse human exposure data and determine the possible health hazards of a specific substance (REACH)

Brussels, 24 November 2010
Andreas Stürer

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Product information format

Format requirements:
- Safety Data Sheet as well as additional information required
- Notification of a SDS file and a PC electronic dataset
- Electronic notification of the required dataset to PICs allows easy electronic data import, validation, presentation, statistical analysis, ...
- Use of XML, PDF and/or other techniques/tools

Brussels, 24 November 2010
Christophe Dupriez

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How will Poisons Centres be affected?

- (Hazardous) Products will be newly classified and labelled
  - communication with public/physician
    - transitional periods with old and new hazard classification
  - products can be classified as more hazardous than before
  - product documentation:
    - Safety Data Sheets with old and new classification, or both!
  - not really affecting the everyday advising

- Harmonisation of product information/notification in the EU
  - possible change in the notified product information quality
  - a new electronic data exchange format
  - put effort in (EU and/or PC) tools to handle the notified product information

Brussels, 24 November 2010

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CLP Regulation

By DG Enterprise & Industry

Lead by Klaus Berend and Karola Grodzki
- April 1st 2011  Brochure – Workshop Report published
- June 15th 2011  1st stakeholder meeting, agenda:
  1. required information quality, esp. composition
  2. need for unique company / product identifier
  3. possibilities to harmonise MS procedures
- Autumn 2011  2nd stakeholder meeting
- Jan 20th 2012  End date of review cf. article 45(4)
  Report to Commission
- 2012-2015  Establish information requirements and format
  Implementation (practically / regulatory)

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Does CLP article 45 apply to other products?

=> YES, to hazardous Plant Protection Products
  => old directive: had no article on product notification to PC
  => new regulation: has no article on product notification to PC

=> YES, to hazardous Biocidal Products
  => old directive: had an article on product notification to PC, but no details,
    similar to CLP regulation art 45 (1-3)
  => new regulation: has an article on product notification to PC, that only
    contains a reference to article 45 of the CLP regulation

=> NO, to Cosmetic products
  => new regulation: product notification to PC is clearly defined in art 13!!
Cosmetic Products Regulation

CPNP ad hoc WG on Frame Formulations (M Mostin)

Frame Formula declaration
Or
Full formula declaration

But additional rules apply to:
- Products of concern
- Substances of concern

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Cosmetic Products Regulation

CPNP ad hoc WG on Frame Formulations (M Mostin)

- Extensive update of the Frame Formulation Declaration System (2011)
  - frame formulation based declaration becomes obligatory!
  - update of all the Frame Formulations (now: 137 FF!)
  - update of the list of products of concern, requiring full declaration
    (e.g. nail varnish removers, tooth whitener)
  - update of the rules for the ingredients of concern, e.g. ethanol
  - enforced workflow in CPNP to guarantee correct and complete data entry!!!

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Cosmetic Products Regulation

CPNP ad hoc WG IT-related issues (P Brekelmans)

- Available information dictated by text of article 13 of the Regulation
  - unique company ID, Product Identification Element
  - product versioning, i.e. easily detect changes in the formula of the product
  - enforced workflow of Frame Formulations, allow no escape routes
  - full declaration send as a picture (PC want structured data!)
  - harmonise with EAPCCT guidelines (notification of hazardous mixtures, CLP)
  - new elements, e.g. product kits

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Cosmetics Regulation

How will Poisons Centres be affected?

- Online search for information on cosmetic products
  - no download and import in local systems
  - only download of the selected product as PDF
  - only storage of product files belonging to cases

- Download of information on cosmetic products to local systems
  - download of daily bulk file and of pictures (label / full declaration)
  - (selected) import of data into local systems
  - adapt/develop local systems to store/maintain product data

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Thanks! Questions?

I hope you survived it, otherwise ....

H-statements and P-statements

Interesting are:

P310 - immediately call a POISON CENTER or doctor/physician
P311 - Call a POISON CENTER or doctor/physician
P312 - Call a POISON CENTER or doctor/physician: If you feel unwell
P342 + P311 - if experiencing respiratory symptoms: Call a POISON CENTER or a doctor/physician

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REACH regulation: Safety Data Sheets

Improvement of SDS quality?

- 3. Composition
  - only hazardous ingredients above thresholds
  - undefined, wide concentration ranges

- 11. Toxicological information
  - information on toxicokinetics, metabolism and distribution
  - information consistent with REACH registration, Chemical Safety Report
  - for each (health) hazard class: not present, why not
  - toxicological properties: of mixture as a whole or of hazardous ingredients

- Annex: exposure scenario’s
  - probably not providing useful information

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