European harmonisation of product notification - Status 2014

Ronald de Groot

Dutch National Poisons Information Center
University Medical Center Utrecht
The Netherlands
Poisons Centers

Informing the public and/or medical personnel about symptoms and treatment of acute intoxications

Detailed product information necessary!
Preparations Directive 1999/45/EC, article 17

The appointed bodies shall have at their disposal all the information... to carry out the tasks for which they are responsible.

This information shall include the chemical composition of mixtures...

Differently implemented in EU Member States:
- Requirements on composition/concentration
- Notification forms
- Methods of electronic notification

HARMONISATION!
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.

- 20 January 2012: EC Review
- Harmonising information and format
- Annex to the Regulation

Lead: European Commission DG Enterprise & Industry
Stakeholders

EAPCCT WG on Poisons Centres Activities / European Regulatory Issues

Member State governmental authorities

Industry
Stakeholder discussions

2007
- Dutch Poisons Center report
  Resulting in CLP article 45(4)

2009
- Introductory meeting: COM, PC

2010
- 3 meetings: COM, PC, GA
- EAPCCT guidelines 2010
- Stakeholder workshop

2011
- 2 meetings: COM, PC, GA, IND
- Discussion on CIRCA website

2012
- Review cf. article 45(4)
- CARACAL meeting: support MS
- 1 meeting: COM, PC, GA, IND

Harmonisation:
- possible
- supported by MS
Stakeholder discussions

2013

• 1 meeting: COM, PC, GA, IND
• EAPCCT guidelines 2013
• **Working Groups on**
  – Unique Formula Identifier
  – Product Category System
  – Industrial mixtures

2014

• **CARACAL meeting**
  – EC Working Paper Ca/06/2014
• Stakeholder comments until May
• Questionnaire: cost-benefit analysis

Information on harmonisation project:
Information requirements

Product identifier
- Complete trade name(s) of the product
- Unique Formula Identifier (UFI)
- Other identifiers

Product category
- **Intended use (Product category code)**
- Consumer, professional, industrial use

Contact details of the submitter

Contact details for rapid access (24/7)

Classification of the mixture and label elements
- Hazard class and category
- Hazard pictograms
- Signal word
- Hazard statements
- Precautionary statements

Toxicological information
- as in Section 11 of Safety Data Sheet

Additional Information on the mixture
- Colour
- pH
- Physical state (solid, liquid, gas)
- Packaging (type and size)

**Composition**
- Chemical name of the substance
- CAS number, EC number
- **Concentration (exact or range)**

Notification update

Exemptions/reduced requirements

Grouped submission
Composition – components in mixture

The following components shall be indicated:

• classified for health or physical hazards:
  – all components in concentration $\geq 0.1$
  – identified components in concentration $< 0.1$

• not classified for health or physical hazards:
  – all components in concentration $\geq 1$
Composition – concentration of component

CLP Regulation (EC) No 1272/2008

Health hazard classes

- Acute toxicity Oral
- Acute toxicity Dermal
- Acute toxicity Inhalation
- STOT* - single exp
- STOT* - repeated exp
- Aspiration hazard
- Skin corrosion/irritation
- Eye damage/irritation
- Respiratory sensitisation
- Skin sensitisation
- Carcinogenicity
- Mutagenicity
- Reproductive toxicity

* Specific Target Organ Toxicity

Hazardous components of major concern for emergency health response:
- Exact percentages
- Alternatively: narrow ranges

All other components:
- Wider ranges
Composition – concentration of component

1 Hazardous components of major concern for emergency health response

<table>
<thead>
<tr>
<th>Exact concentration (%)</th>
<th>Maximum width of the concentration range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 25 - ≤ 100</td>
<td>- 5 % units</td>
</tr>
<tr>
<td>&gt; 10 - ≤ 25</td>
<td>- 3 % units</td>
</tr>
<tr>
<td>&gt; 2 - ≤ 10</td>
<td>- 1 % units</td>
</tr>
<tr>
<td>&gt; 1 - ≤ 2</td>
<td>- 0.5 % units</td>
</tr>
<tr>
<td>&gt; 0.1 - ≤ 1</td>
<td>- 0.3 % units</td>
</tr>
<tr>
<td>&gt; 0 - ≤ 0.1</td>
<td>- 0.05 % units</td>
</tr>
</tbody>
</table>

Example:
Exact concentration 26%
Falls in > 25 - ≤ 100 range
Allowed # of units: 5
Can be notified as:
21-26%, 22-27%, 23-28 %, 24-29%, 25-30%, 26-31%
but also 25-27% or even 26%

• Sufficient confidentiality
• Reduce renotification after small changes in ingredient concentration
For all other components in the mixture:

<table>
<thead>
<tr>
<th>Exact concentration (%)</th>
<th>Maximum width of the concentration range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 40 - ≤ 100</td>
<td>- 20 % units</td>
</tr>
<tr>
<td>&gt; 10 - ≤ 40</td>
<td>- 10 % units</td>
</tr>
<tr>
<td>&gt; 1 - ≤ 10</td>
<td>- 3 % units</td>
</tr>
<tr>
<td>&gt; 0.1 - ≤ 1</td>
<td>- 0.5 % units</td>
</tr>
<tr>
<td>&gt; 0 - ≤ 0.1</td>
<td>- 0.1 % units</td>
</tr>
</tbody>
</table>
Composition – requirements in EU countries

**COMPOSITION**

- SDS
  - Thresholds for hazardous substances
- Harmonisation
  - Thresholds for all substances
- Cosmetics without FF
  - Exact composition (no thresholds)

**CONCENTRATION**

- SDS
  - No guidelines
- Harmonisation
  - Specified ranges
- Cosmetics without FF
  - Exact concentration and specified ranges
- Detergents
  - Exact concentration
Exemptions / reduced requirements

Exemptions

- Scientific research and development
- Product and process oriented Research and Development (PPORD)

Reduced submission requirements

- Mixture for industrial use only
  - REACH code SU3
    - Notification of SDS
    - Rapid access to detailed product information
      24/7 telephone number

A study to evaluate the workability of this solution will be conducted
**Unique Formula Identifier**

**Identification of the mixture is important!**

- **UFI changes with formula change**
- **Date-time stamp to distinguish datasets with same formula**
Unique Formula Identifier

Unique code linking unambiguously a submitted composition to a specific mixture on the market

Solution to mixtures in mixtures problem:

Product Y
- Substance 5%
- **Product X** (UPI: XXXX-XXXX-XXXX-XXXX) 60%
  - Substance 15%
  - Substance 20%

**Product X** (UPI: XXXX-XXXX-XXXX-XXXX)
- Substance 12%
- Substance 88%
Unique Formula Identifier

UFI Generator: http://upi.toxalert.fr

- Unique identifier: allows companies to assign UFI themselves
- > 39 millions of formulation codes per VAT-number
- Excepted letters & included checksum key: no confusion
- No business information revealed
Unique Formula Identifier

Identification on the label
- Printed on packaging or label
- BfR project: CEN standardisation EN 15178
  Product identification element near barcode + symbol

UFI part of cost-benefit study
- Necessary for product identification + mixture in mixture
- Burden for companies
- New equipment needed some companies: a transition period necessary

Adaptations of labelling rules in CLP Regulation necessary? Implications on legislative procedures?
Product category system

Hierarchical system:
- Chemical products
  - Cleaning product
    - Dishwasher detergents

- TDI system first two levels
- Categories beyond that levels:
  – REACH Product Category codes
  – other use descriptions

Uses:
- Statistically assess poison incidents across EU Member States
- Identify risks and to propose measures for preventing exposures
eXtensible Markup Language (XML)

- Automatic control of validity and quality of data before data import

Possible future step:
- Integration in SDS creating software

Forthcoming
WG Electronic notification format

XML:
- a sequence of information elements
- Each element surrounded by <tag> and </tag>
- Sub-elements can be introduced in any elements
European product database

Industry
• Centralised database is preferred

Poisons Centers
• Information in local databases important (download option)

Commission
• Most important: harmonised XML format
• Possibility will be explored: cost / benefit, where to develop, security, effect on SME, languages
• If developed: additional resources necessary
• Experience from CPNP project important
Next steps

2014
• CARACAL: Preliminary results cost-benefit study

2015
• CARACAL: draft proposal Commission Regulation
• Formal proposal to the REACH committee
• Working groups?
  – Electronic notification format
  – Product category system

2015-2016
• Official publication?