



UMC Utrecht

European harmonisation of product notification- Status 2014

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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

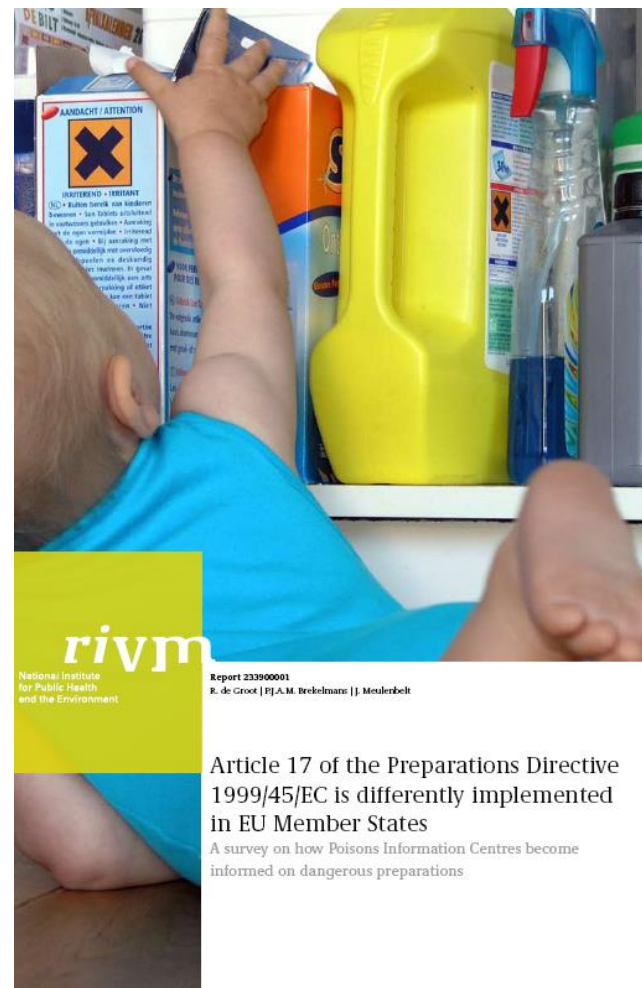
The appointed bodies shall have at their disposal all the information ... to carry out the tasks for which they are responsible

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!



CLP Regulation 1272/2008, article 45(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**

- 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



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals, metals, mechanical, electrical and construction industries; Raw materials
Chemicals - Classification & Labelling, Specific Products, Competitiveness

Harmonisation of Information for Poison Centres

Review according to Article 45(4) of Regulation (EC) No 1272/2008 on classification,
labelling and packaging of substances and mixtures

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:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/poison-centres/index_en.htm



EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries

REACH
Chemicals Industry
ENVIRONMENT DIRECTORATE-GENERAL
Green Economy
Chemicals

Brussels, 20 March 2013
Doc. **CA/06/2014**

14th Meeting of Competent Authorities for REACH and CLP (CARACAL)

2-3 April 2014

Centre A. Borschette, Brussels, Belgium

Concerns:

Harmonisation of Information for Poison Centres; working paper for a possible Commission proposal according to Article 45(4) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

WORKING PAPER

**REQUIREMENTS FOR THE SUBMISSION OF INFORMATION
RELATING TO EMERGENCY HEALTH RESPONSE**



EC Working Paper Ca/06/2014

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	Categories
Acute toxicity Oral	1 3 4
Acute toxicity Dermal	1 3 4
Acute toxicity Inhalation	1 3 4
STOT* - single exp	1 2 3
STOT* - repeated exp	1 2
Aspiration hazard	1
Skin corrosion/irritation	1 2
Eye damage/irritation	1 2
Respiratory sensitisation	1
Skin sensitisation	1
Carcinogenicity	1AB 2
Mutagenicity	1AB 2
Reproductive toxicity	1AB 2

* Specific Target Organ Toxicity

1

Hazardous components of major concern for emergency health response:

- Exact percentages
- Alternatively: narrow ranges

2

All other components:

- Wider ranges



Composition – concentration of component

1 Hazardous components of major concern for emergency health response

Exact concentration (%):	Maximum width of the concentration range:
> 25 - ≤ 100	- 5 % units
> 10 - ≤ 25	- 3 % units
> 2 - ≤ 10	- 1 % units
> 1 - ≤ 2	- 0.5 % units
> 0.1 - ≤ 1	- 0.3 % units
> 0 - ≤ 0.1	- 0.05 % units

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



Composition – concentration of component

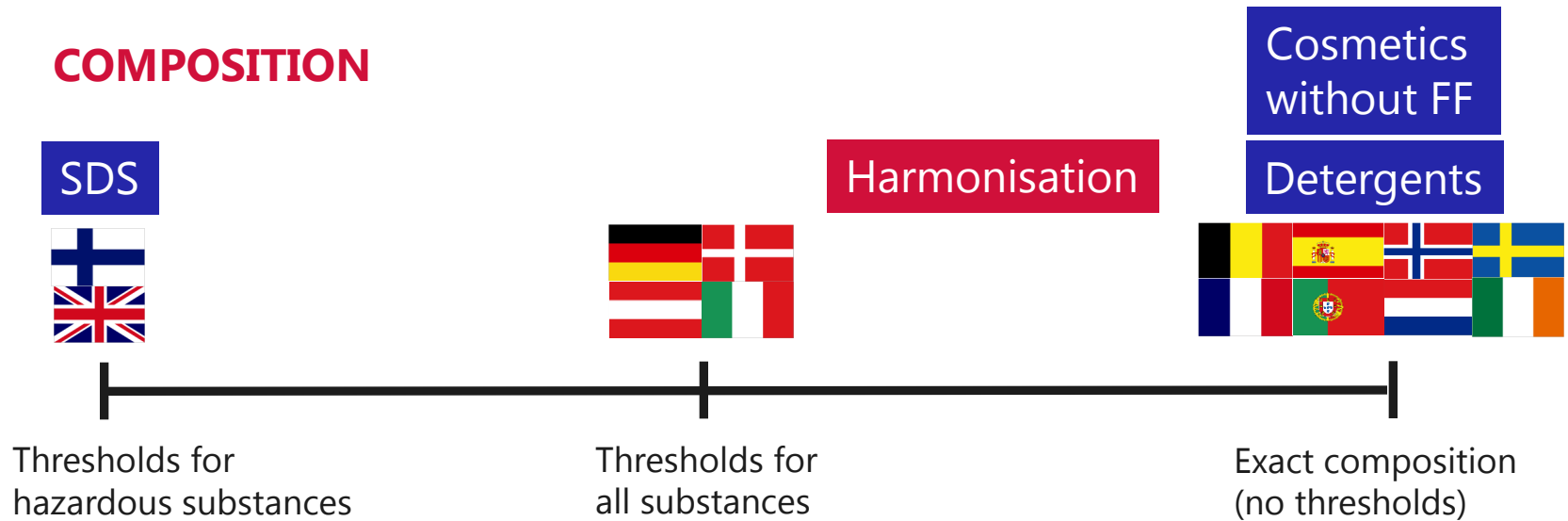
2 For all other components in the mixture:

Exact concentration (%):	Maximum width of the concentration range:
$> 40 - \leq 100$	- 20 % units
$> 10 - \leq 40$	- 10 % units
$> 1 - \leq 10$	- 3 % units
$> 0.1 - \leq 1$	- 0.5 % units
$> 0 - \leq 0.1$	- 0.1 % units

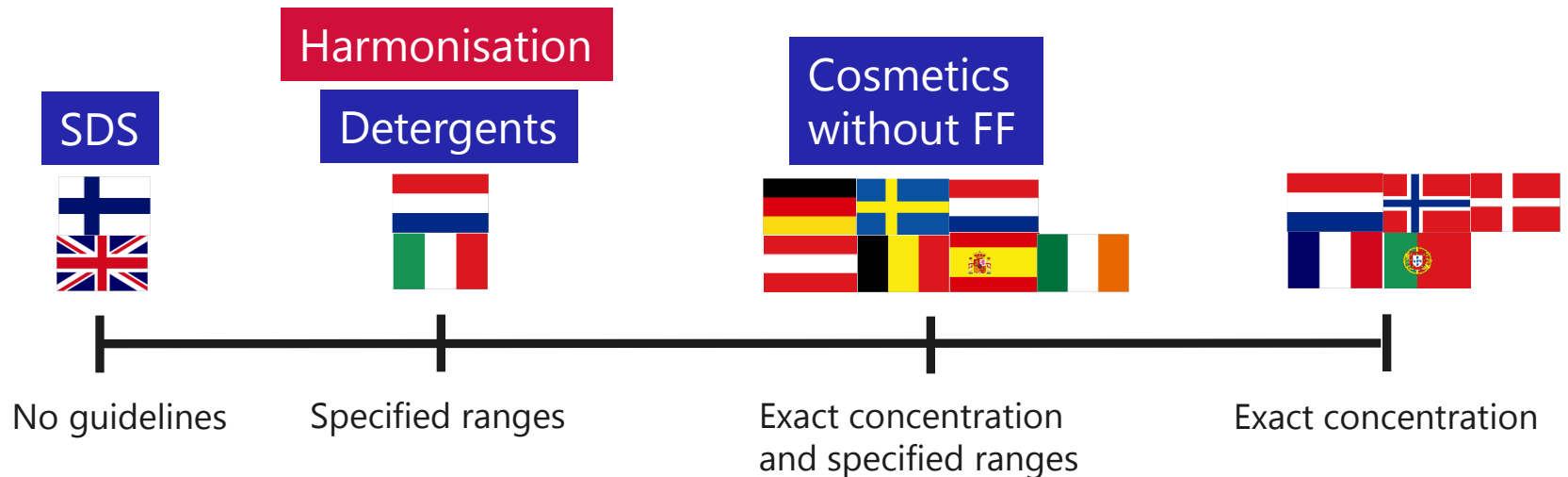


Composition – requirements in EU countries

COMPOSITION



CONCENTRATION



Exemptions / reduced requirements

Exemptions

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

Reduced submission requirements

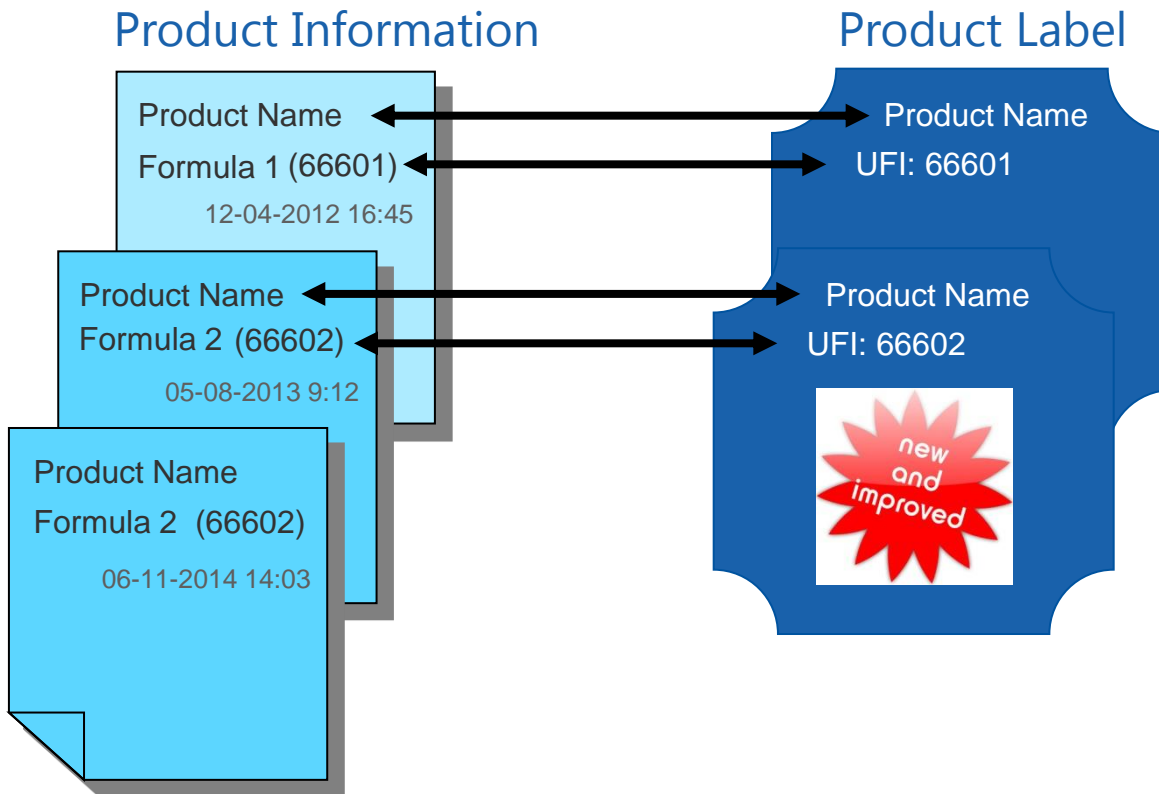
- Mixture for industrial use only
REACH code SU3
 - Notification of SDS
 - Rapid access to detailed product information
24/7 telephone number

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



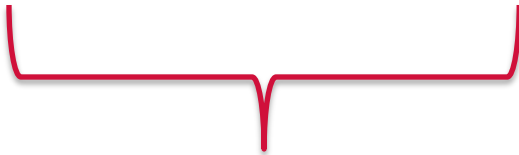
Unique Formula Identifier

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>

UFI generator - v1.1




Country : VATN Length : 12

VAT identification number : Format :

Formulation code : Format :

UFI : - - - 

UFI validator - v1.1

UFI :   

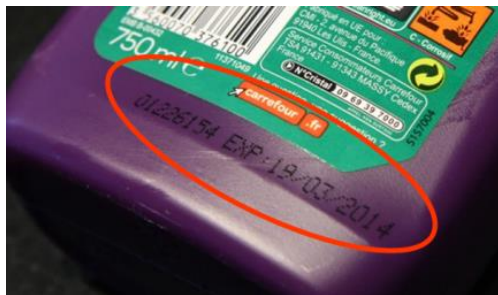
- Unique identifier: allows companies to assign UFI themselves
- > 39 millions of formulation codes per VAT-number
- Excepted letters & included checksum key: no confusion
- No business information revealed



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



Annual European poisoning report?



Electronic notification format

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

```
<submission>
  <date>2010-11-24</date>
  <market>be</market>
  <submitter>
    <name>Detergents Company</name>
    ...
  </submitter>
  <mixture>
    <product-id>...</product-id>
    <trade-name>Detergent SUPER</trade-name>
    ...
    <composition>
      <ingredient>
        <cas>7601-54-9</cas>
        <min>3</min>
        <max>10</max>
        <unit>percent</unit>
      </ingredient>
    </composition>
  </mixture>
  ...
</submission>
```

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?*

