

Harmonisation of product notification

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Dutch Poisons Information Center



Universitair Medisch Centrum
Utrecht

Poisons Centres

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



Product



Amount



Patient

Detailed product information necessary!

Product information requirements

Safety Data Sheet + Composition file

Exact composition: all ingredients without concentration threshold

- 1 Exact concentrations of all ingredients
- 2 Exact concentration for ingredients in hazard class: T⁺, T, C, Xi, Xn
CLP Regulation: all health hazard classes
Defined concentration ranges (see below) for the other ingredients
- 3 Defined concentration ranges:
<0,1%, 0,1-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-50%, 50-75%,75-100%
Alternative: <0,1%, 0,1-1%, 1-5%, 5-10%, 10-15%, 15-30%, 30-60%, 60-100%

E-mail: productnotificatie@umcutrecht.nl

[Contact](#) [FAQ](#) [Notification requirements](#) [UMCU home](#) [NVIC home](#) [A](#) [A](#) [A](#)



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Utrecht

Product Notification

National Poisons Information Center



Login name

Password



New code

Enter the code shown above

→ Login

Forgot password

Companies introducing hazardous products on the Dutch market are obliged to notify product information to the National Poisons Information Centre (NVIC).

The product information is used by the NVIC to inform medical personnel (physicians, veterinarians, pharmacists) about symptoms and treatment of accidental intoxications with the products. Especially knowledge of the exact composition and toxicological properties of the products is necessary to adequately perform this task.


With this secure website, product information can easily be notified. The requirements are described under *Notification requirements*. The notified information will be treated in strict confidence and will not be communicated to third parties.

To receive a user account, please provide the information as stated under *Contact*.

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Utrecht

Product Notification

National Poisons Information Center

[Clear all input fields](#) [Logoff](#)

Create product upload list

Choose: New Modified Expired

Product name:
Super decaaser

MSDS file: [Bladeren...](#) **Composition file:**

[Add product](#) to upload list

You have already selected:

Reason	Product name	MSDS file	Composition file	
N	All purpose cleaner	All purpose cleaner MSDS.pdf	All purpose cleaner Composition.pdf	Remove
N	Laundry detergent	Laundry detergent MSDS.pdf	Laundry detergent Composition.pdf	Remove

Upload for: TEST Leverancier
Upload by: TEST Melder
E-mail to: r.degroot-5@umcutrecht.nl

[← Back](#) to renew the e-mail address

[→ Continue](#) to proceed with uploading (first check the information you have entered!)

Bestand selecteren

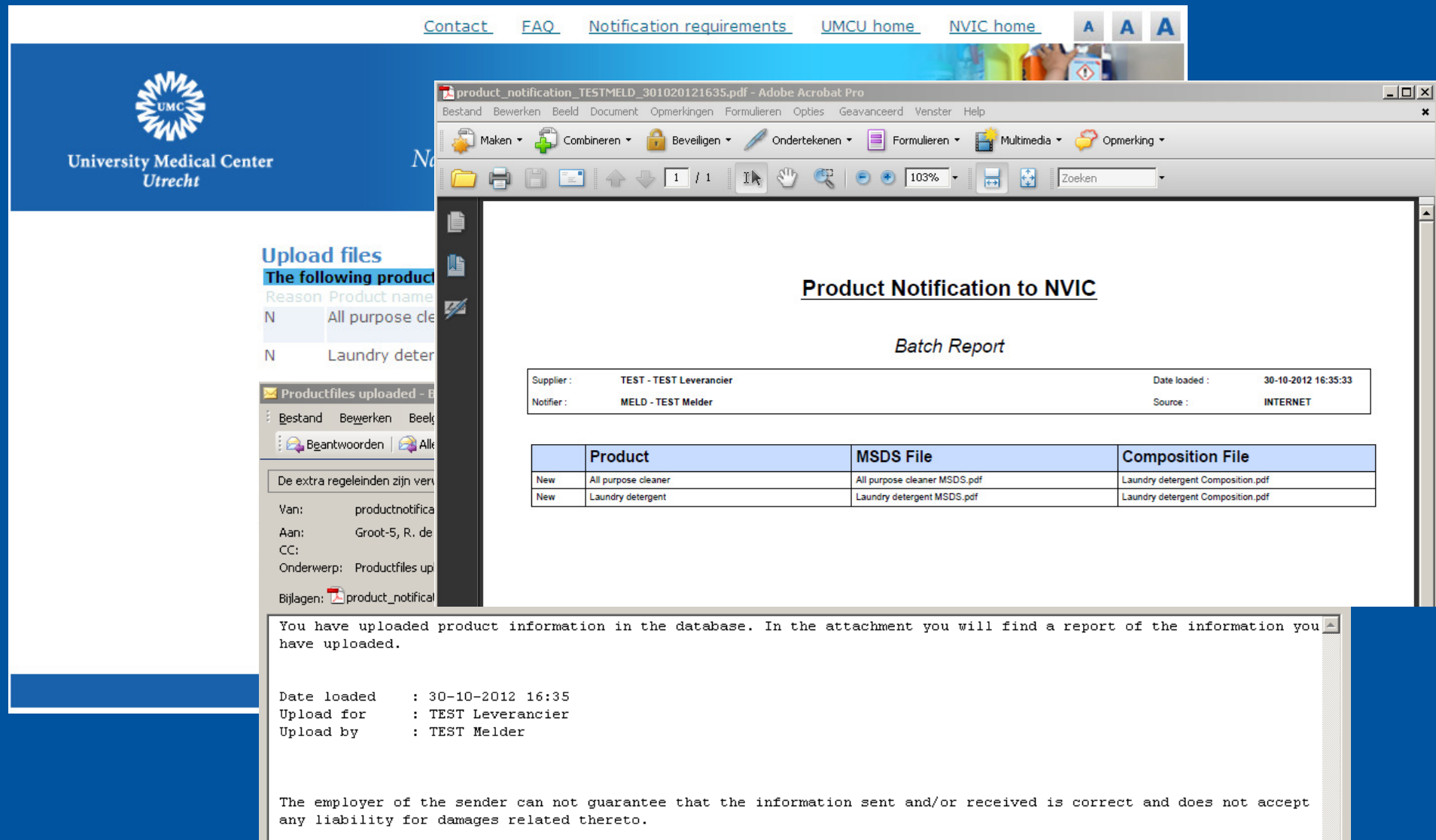
Zoeken in: Productinformatie

- All purpose cleaner Composition.pdf
- All purpose cleaner MSDS.pdf
- Laundry detergent Composition.pdf
- Laundry detergent MSDS.pdf

Bestandsnaam: [Openen](#)

Bestandstypen: Alle bestanden (*.*) [Annuleren](#)

E-mail: productnotificatie@umcutrecht.nl



The screenshot displays a web application interface for product notifications. The main content area shows a PDF report titled "Product Notification to NVIC" and "Batch Report". The report includes a table with columns for Product, MSDS File, and Composition File. The report also contains a table with supplier and notifier information.

Product Notification to NVIC

Batch Report

Supplier :	TEST - TEST Leverancier	Date loaded :	30-10-2012 16:35:33
Notifier :	MELD - TEST Melder	Source :	INTERNET

	Product	MSDS File	Composition File
New	All purpose cleaner	All purpose cleaner MSDS.pdf	Laundry detergent Composition.pdf
New	Laundry detergent	Laundry detergent MSDS.pdf	Laundry detergent Composition.pdf

The email client window shows the following details:

Productfiles uploaded - B

Beantwoorden | Alk

De extra geregeleinden zijn ver

Van: productnotifica

Aan: Groot-5, R. de

CC:

Onderwerp: Productfiles up

Bijlagen: product_notifical

You have uploaded product information in the database. In the attachment you will find a report of the information you have uploaded.

Date loaded : 30-10-2012 16:35
Upload for : TEST Leverancier
Upload by : TEST Melder

The employer of the sender can not guarantee that the information sent and/or received is correct and does not accept any liability for damages related thereto.

Harmonisation of product information



CLP Regulation (EC) No 1272/2008, article 45
(Preparations Directive 1999/45/EC, article 17)

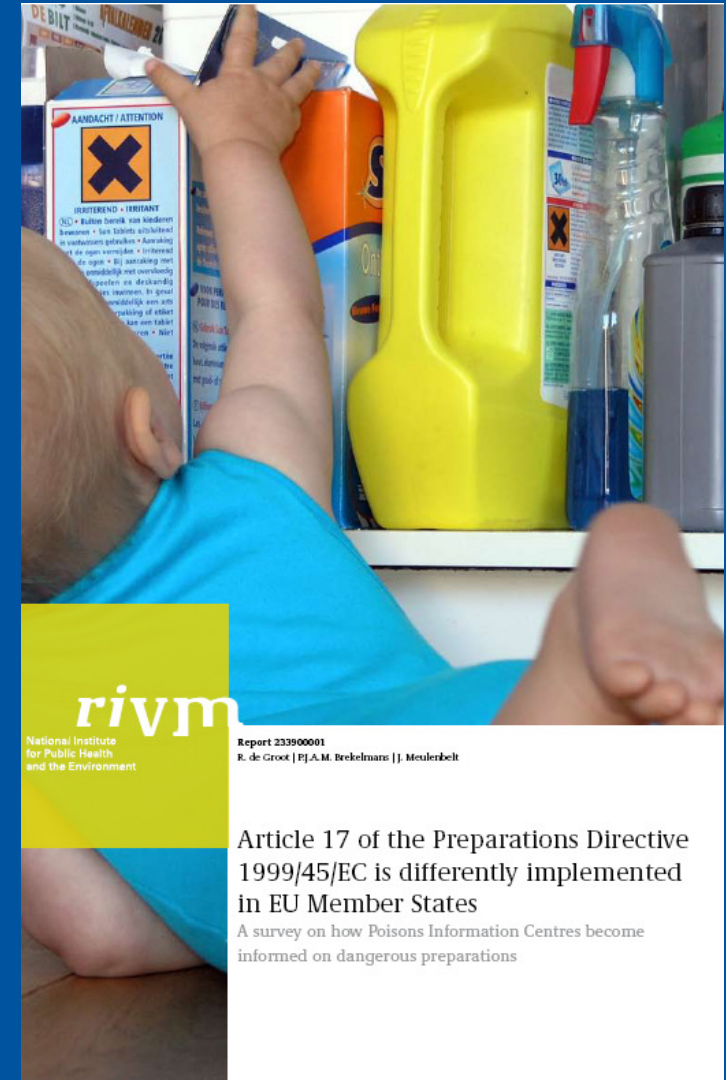
The appointed bodies shall have at their disposal all the information ... to carry out the tasks for which they are responsible

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!



Harmonisation of product information

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



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

Lead by: **European Commission DG Enterprise & Industry**

Stakeholders



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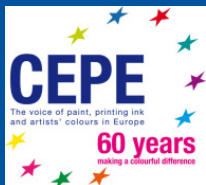
EAPCCT WG on Poisons Centres Activities / European Regulatory Issues



Member State governmental authorities



Industry



Stakeholder discussions

2009

- Introductory meeting: COM, PC

2010

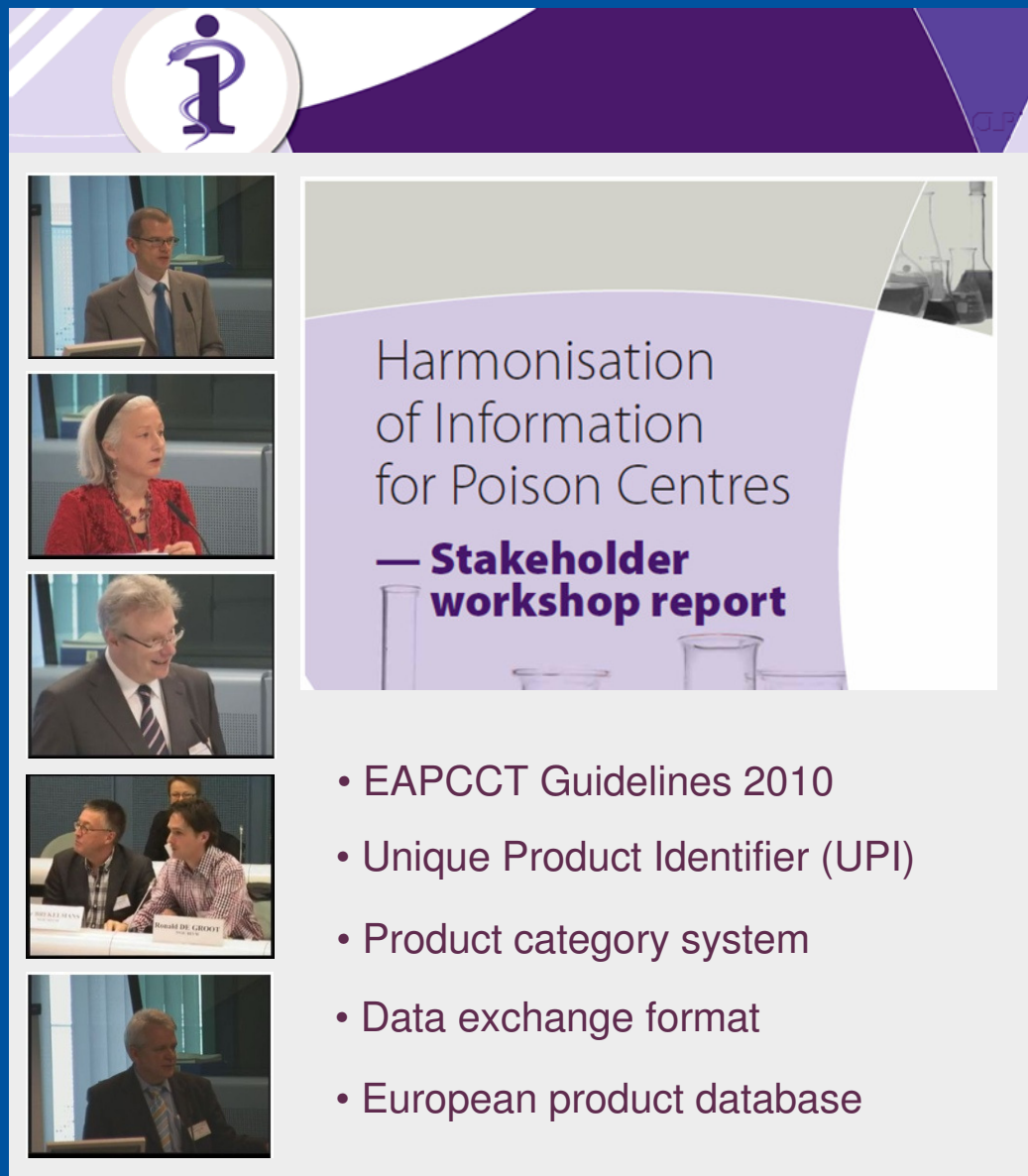
- 3 meetings: COM, PC, GA
- Stakeholder workshop

2011

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

2012

- Review cf. article 45(4)
- CARACAL meeting



The image shows the cover of a report titled "Harmonisation of Information for Poison Centres — Stakeholder workshop report". The cover features a purple and white color scheme with a logo of a person with a caduceus. Below the title, there are five small photographs showing participants in a meeting. To the right of the photographs, there is a list of bullet points.

Harmonisation
of Information
for Poison Centres
— **Stakeholder
workshop report**

- EAPCCT Guidelines 2010
- Unique Product Identifier (UPI)
- Product category system
- Data exchange format
- European product database

EAPCCT Guidelines 2010



COMPANY INFORMATION

IDENTIFICATION OF THE MIXTURE

- Mixture identifiers
- Unique Product Identifier

COMPOSITION

- Substances in the mixture
- Substance concentrations
- Renotification rules

CATEGORISATION

CLASSIFICATION

PACKAGING

PHYSICAL/CHEMICAL CHARACTERISTICS








TOXICOLOGY

OTHER INFORMATION

EAPCCT Guidelines 2010 - composition



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	 2
Eye damage/irritation	 2
Respiratory sensitisation	1
Skin sensitisation	1
Carcinogenicity	1AB 2
Mutagenicity	1AB 2
Reproductive toxicity	1AB 2

Complete list of ingredients

Exact concentrations for substances with specific hazard classification

For all other substances in the mixture concentration bands:

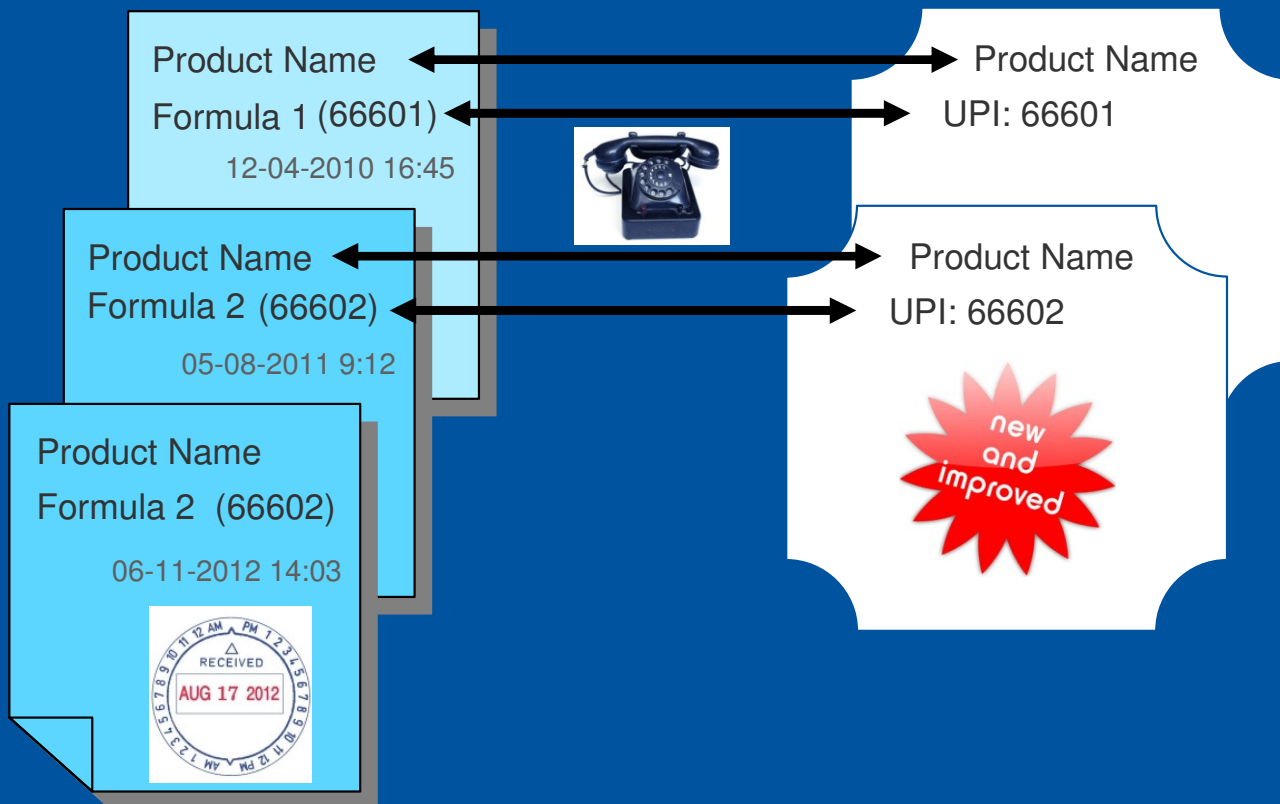
0-0,1%, 0,1-1%, 1-3%,
3-10%, 10-20%, 20-30%,
30-50%, 50-75%, >75%

Unique Product Identifier

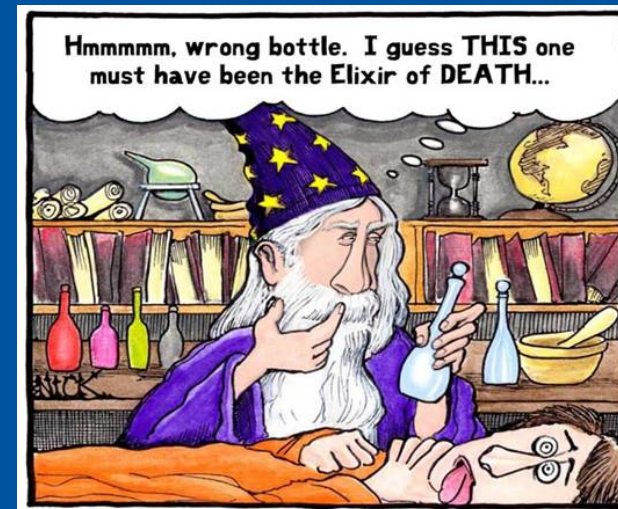
Identification of the mixture is important!

Product Information

Product Label



- UPI changes with formula change
- Date-time stamp to distinguish datasets with same formula



Unique Product Identifier



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Proposal of EAPCCT Working Group

- Allows companies to assign UPI themselves

Input: country code, VAT number, product code

Output: UPI

UPI Generator: <http://upi.toxalert.fr>



BfR project: CEN standardisation EN 15178

- Product identification element near barcode + symbol



Data exchange format

European product database

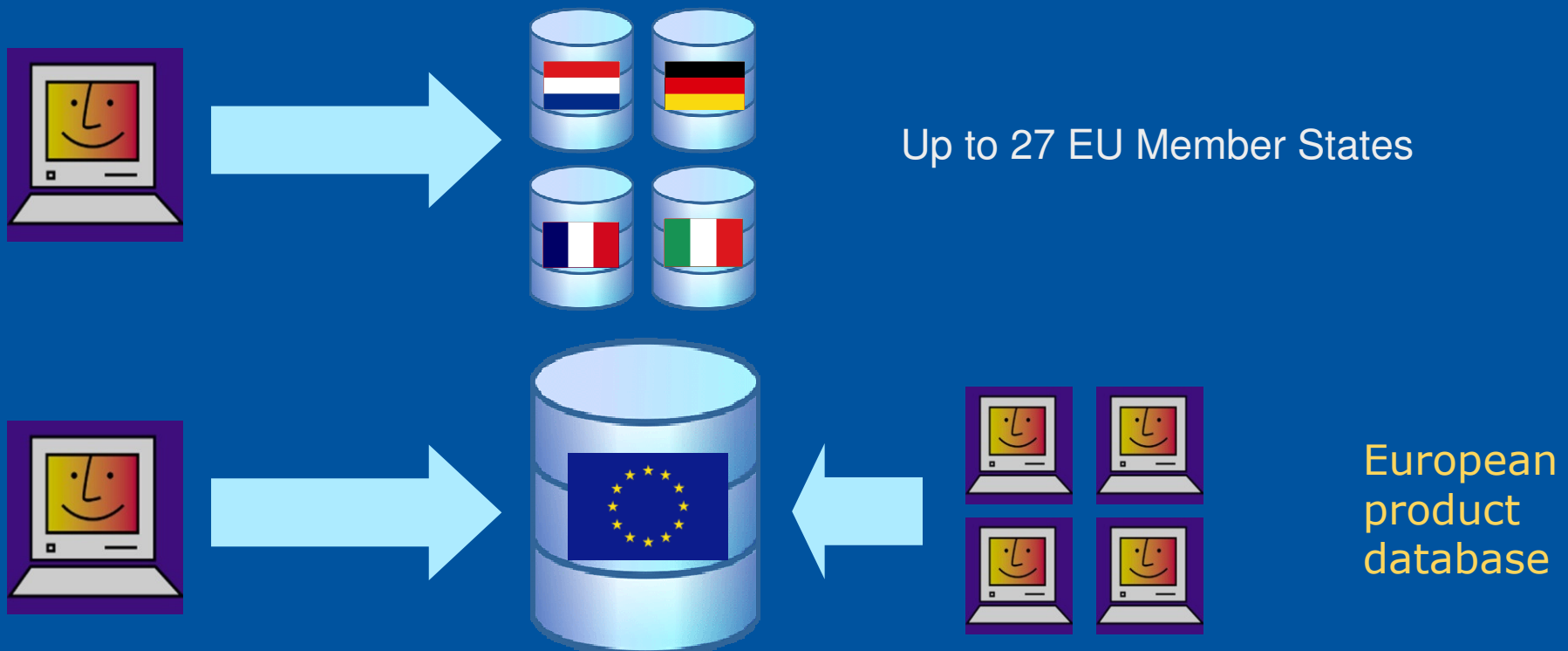


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Electronic data exchange format

eXtensible Markup Language (XML)

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





Stakeholder views

Requirements on composition

Adaptations to EAPCCT guidelines

- Small ranges for substances with specific classification
- Concentration threshold for non-classified substances

European product database

Most important: harmonised XML format

Possibility will be explored:
cost / benefit, where to develop, security,
effect on SME, languages

Experience from Cosmetics database

Unique Product Identifier (UPI)

Cost / benefit analyses

Analyse necessary adaptations of
labelling rules in CLP Regulation



Review according to Article 45(4)



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

20 January 2012

**Harmonisation of
product notification
feasible!**

CARACAL (Competent Authorities for REACH and CLP)

21-23 March 2012

MS Reactions from:

The Netherlands, Finland, Sweden, Austria,
Cypres, Belgium, Germany, Italy, UK, Portugal

All in favour of harmonisation!



Next steps



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COM Working Group to continue the discussion

Next meeting: 29 November 2012

Latest at the end of 2013: finalise the discussions

2014: draft proposal for an Annex to the CLP Regulation



Thank you for your attention!



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EXTRA SLIDES

EAPCCT Guidelines 2010



COMPANY INFORMATION

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

IDENTIFICATION OF THE MIXTURE

- Mixture identifiers
- Unique Product Identifier

COMPOSITION

- Substances in the mixture
- Substance concentrations
- Renotification rules

CATEGORISATION

- Product Category
- Consumer / Professional only use

CLASSIFICATION

- Classification
- Label elements

PACKAGING

- Type(s)
- Size(s)
- Labels

PHYSICAL/CHEMICAL CHARACTERISTICS

- Physical state
- pH
- Total reserve acidity/alkalinity

TOXICOLOGY

OTHER INFORMATION

EAPCCT dataset

Add. Info

SDS

Unique Product Identifier

AA – XXXX XXXX – YYYY – KK

With

AA :	member state EU identifier (copy from VAT number)
XXXX XXXX :	coded and formatted VAT number
YYYY :	unique identifier guaranteed by the manufacturer or downstream user (formulation code in 32-based number: 1 047 583 possibilities <i>per manufacturer</i>)
KK :	control checksum key

Composition Requirements in EU countries



DUTCH SURVEY 2007

COMPOSITION

SDS



Thresholds for dangerous substances



Thresholds for all substances

EAPCCT



Exact composition

CONCENTRATION

SDS



No guidelines



Specified ranges

EAPCCT



Exact concentration and specified ranges



Exact concentration