The Harmonised European Product Notification according to Article 45 (4) CLP Regulation

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National Poisons Information Centre

(NVIC) [2011- today]

- Project leader Product Notification
- A.o. ICT Coordinator

European Association of Poisons Centres and Clinical Toxicologists

(EAPCCT) [may2016 – today]

- Member of the Board and the Scientific Committee
- Chair of the Working Group on Poisons Centre activities and European Regulatory Issues

Different product notification procedures in EU

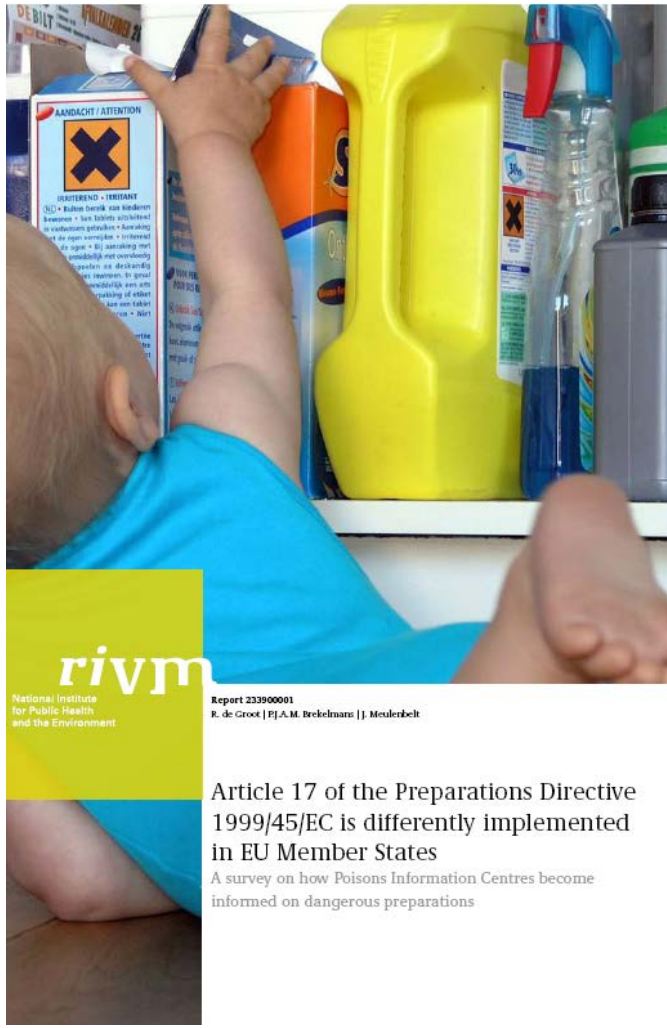
'information requirements not defined in old legislation'

"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

- Product information requirements
- Notification forms
- Methods of (electronic) notification



HARMONISATION!

Different product notification procedures in EU

'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.**

An Jamers

roberto scazzola

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Brussels Area, Belgium | Environmental Services

Current	European Commission DG Enterprise
Previous	ReachCentrum (CEFIC subsidiary company), AECOM Italy, ENSR Italy (now AECOM Italy)
Education	Ca' Foscari University of Venice

Lead: DG GROW

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Stakeholders

'in the harmonisation process'

EAPCCT WG on Poisons Centres Activities / European Regulatory Issues

Member State governmental authorities

Bundesinstitut für Risikobewertung

Industry

Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

Wir gestalten Zukunft.
Verband der Chemischen Industrie e.V.

The European Chemical Industry Council

INTERNATIONAL FRAGRANCE ASSOCIATION

effa european flavour association

60 years

European Crop Protection

Downstream Users of Chemicals Co-ordination group

European Association of Chemical Distributors

Discussion on product information requirements

'looking for a compromise'

First phase 2009-2010

- EAPCCT Guidelines
- Workshop on the harmonisation of information for Poisons Centres

Second phase (2011-2013)

- Stakeholder discussions
- Review cf. article 45(4)

Third phase (2013-2015)

- CARACAL (draft legal text)

Fourth phase (2016)

- REACH committee

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SME'S
Consumer Environmental and Health Technologies
REACH
Chemicals
ENVIRONMENT DIRECTORATE-GENERAL
Green Economy
Chemicals

Brussels, 11 June 2015
Doc. CA/48/2015

18h Meeting of Competent Authorities for REACH and CLP (CARACAL)

Room: 2D, Centre Albert Borschette

23-24 June 2015

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**

Agenda Point: **12**

Action Requested: **For discussion and written comments by 15th July 2015 to Roberto.Scazzola@ec.europa.eu and Fabienne.van-raemdonck@ec.europa.eu**

EU countries vote in favour of the European Commission's proposal to harmonise hazard and safety information for use by Poison Centres

Published on: 21/09/2016

Today, EU countries have voted in favour of a Commission proposal which will improve the availability of information on chemicals, needed in case of poisoning. This harmonisation will lead to better health protection for EU citizens and at the same time save EU producers and importers of chemical mixtures approximately €550 million annually.

In cases of accidental poisoning by hazardous chemical mixtures used in, for example, cleaning products, paints, fuel and pesticides, citizens can call their national poison centre for an emergency health response, which is based on the information provided by the chemicals' manufacturers. Today, each EU country has its own legal requirements defining such information. A chemicals producer selling their products in several EU countries must provide information in multiple formats and to differing degrees of detail. This leads to a high administrative burden for industry and can result in an unequal level of emergency health response among EU citizens.

The proposal will lead to producers and importers of chemical mixtures providing uniform information on the product composition. At the same time, emergency responders in all EU countries will have the same medical information available, which for some countries will allow services to be improved. Through a new uniform product identifier, poison centres will be able to exactly identify the product and its composition, leading to better and more appropriate medical response and reducing unnecessary over-treatment which is often given to be on the safe side.

The Regulation will apply to mixtures for consumer use as of 2020. It also targets mixtures for professional and industrial use, for which requirements apply as of 2021 and 2024, respectively.

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Composition information

'on components in the mixture'

The following mixture components shall be indicated:

- Mixture components classified for health or physical hazards, which:
  - are present in concentrations ≥ 0.1%
  - are identified components in concentrations < 0.1%
    - ➢ Excluding e.g.: impurities/additives of a substance

- Mixture components not classified for health or physical hazards:
  - all components in concentrations ≥ 1%

Composition information

‘on the concentration of mixture components’

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	1A / 1B / 1C / 2
Eye damage/irritation	1 / 2
Respiratory sensitisation	1AB
Skin sensitisation	1AB
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 concentration
- Alternatively:

  narrow conc. ranges

2

All other components:

- Wider conc. ranges

Composition information

‘using narrow concentration ranges for mixture components’

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
≥ 1 - < 10	- 1 % units
≥ 0.1 - < 1	- 0.3 % units
≥ 0 - < 0.1	- 0.1 % 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 for adequate risk assessment
- Sufficient confidentiality
- Reduce renotification after small changes in ingredient concentration

Composition information

‘using wide concentration ranges for mixture components’

2 For all other components in the mixture:

Exact concentration (%):	Maximum width of the concentration range:
≥ 25 - < 100	- 20 % units
≥ 10 - < 25	- 10 % units
≥ 1 - < 10	- 3 % units
≥ 0 - < 1	- 1 % units

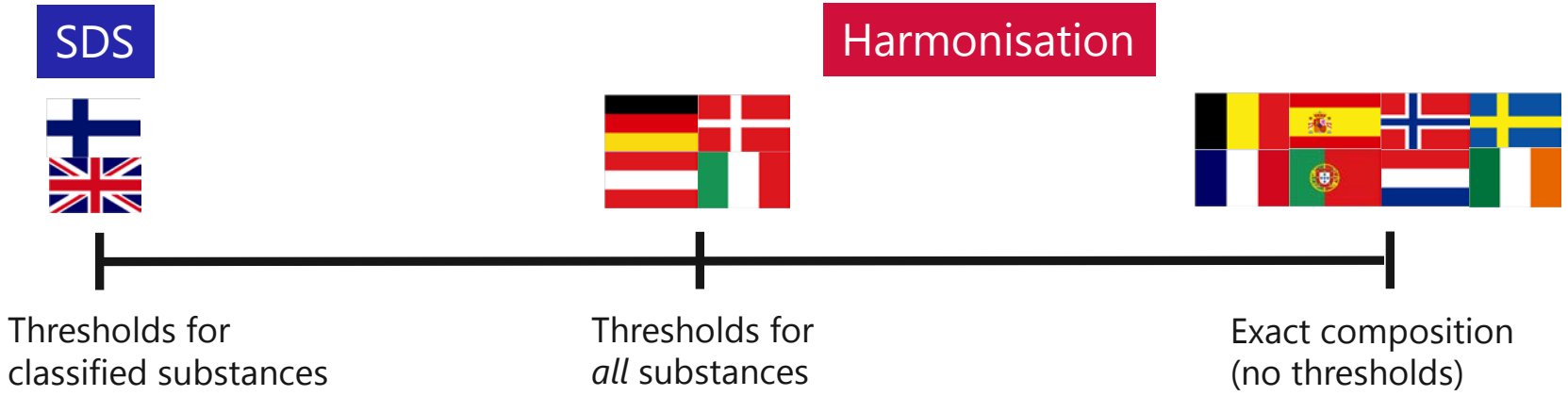
Example:
Exact concentration 50%
Falls in > 25 - ≤ 100 range
Allowed # of units: 20%

Can be notified as:
40-60%, 50-70%, 30-50%, etc

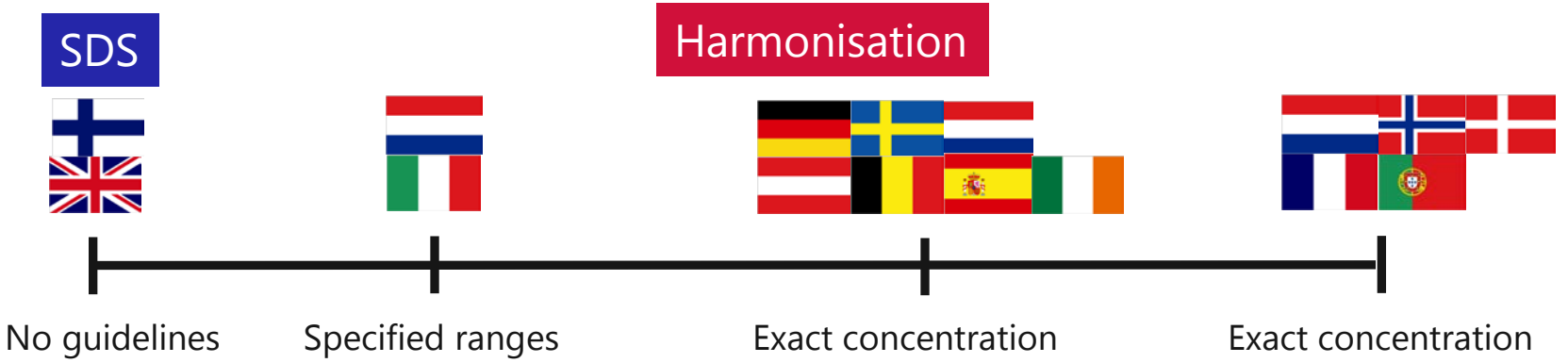
Composition information

'harmonisation results vs current requirements in EU countries

COMPOSITION



CONCENTRATION



Group submission / generic product identifiers

'to reduce submission burden for industry'

The generic product identifiers '**perfumes**', '**fragrances**' and/or '**colouring agents**' can be used if the mixture component:

1. is not classified for any health hazard, and
2. to the extent that the sum of concentrations of mixture components identified with generic product identifiers does not exceed:
   - ✓ 5% for the sum of **perfumes** and **fragrances**, and
   - ✓ 25% for the sum of **colouring agents**.

Group submission of mixture variants e.g. a paint in many different colours, may be grouped, if:

- variants same hazard classification and product categorisation and,
- essentially have the same composition
  (same mixture components in same concentration ranges).

Draft Annex VIII on product notification

'list of information requirements'

Mixture / submitter identification

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

Contact details of the submitter

Contact details for rapid access (24/7)

Classification of mixture and label elements

- Hazard class and category
- Hazard pictograms codes
- Signal word
- Hazard statements codes
- Precautionary statements codes

Toxicological information

- as in Section 11 of Safety Data Sheet

Blue: not on SDS or less detailed

Additional Information on mixture

- Colour
- pH
- Physical state (solid, liquid, gas)
- Packaging (type and size)
- Intended use
  (Product Categorisation Code)
- Consumer, professional, industrial use

Identifiers of mixture components

- Chemical name of the substance
- CAS number, EC number
- **UFI (mixture in mixture)**

Concentration of mixture components

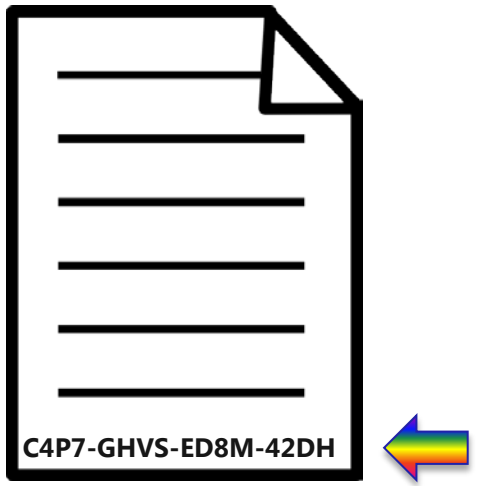
Identifiers of mixture components

- Hazard class and category

Unique Formula Identifier

‘Identification of the mixture is important!’

Product information at Appointed body



Unique Formula Identifier

'UFI characteristics'

The UFI:

- is a unique code unambiguously linking a submitted composition to a specific mixture on the market
- changes with a formula change
- is affixed on the label

- has a 4x4 format of 16 characters and numbers:
  UFI: C4P7-GHVS-ED8M-42DH

- is calculated from the VAT number and a formulation code
- can be generated with an UFI algorithm/generator:
  270 million unique codes per VAT

Unique Formula Identifier

'used to identify Mixtures-In-Mixtures (MIM)'

Problem:

Companies regularly do not get information on the composition of a mixture used to create a new mixture.

Solution:

Supply UFI/supplier info of the mixture.

Product Y

- Substance 5%
- Product X (UFI: XXXX-XXXX-XXXX-XXXX) 60%
- Substance 15%
- Substance 20%

Product X (UFI: XXXX-XXXX-XXXX-XXXX)

- Substance 12%
- Substance 88%

Product Category System

'for statistical analysis and preventative measures'

Hierarchical system:

- Chemical products
  - Cleaning products
    - Dishwasher detergents

Annual European poisoning report?

Characteristics:

- Scope: hazardous mixtures
- Backbone: German categorisation system
- Building blocks: sector specific product categories
- Dimension: intended use (/toxicology?)

Uses:

- Statistically assess poison incidents across EU Member States
- Identify risks and to propose measures for preventing exposures

Update of the product information

‘when important mixture information changes’

A submission update is required:

- when the mixture product identifier changes (name, UFI);
- when the mixture classification changes;
- When new toxicological information becomes available;
- if a change in the composition fulfils one of the criteria:
    - Addition / substitution /deletion of mixture components;
    - Change in concentration beyond the range provided in previous submission;
    - The exact concentration changes beyond the allowed variation.

Scope of the legislation

'included/excluded mixtures'

Applies to:

- ✓ Mixtures classified as hazardous based on health or physical effects
  - ✓ including: biocidal and plant protection products
  - ✗ excluding: '*gases under pressure*' and *'(unstable) explosives*'

    (and not classified for any other hazard)

- ✓ Mixtures for consumer use, professional use and industrial use
  - ✗ Reduced submission requirements mixture for industrial use only
    - REACH code SU3
    - Notification of SDS
    - Rapid access to detailed product information (24/7 telephone number)

Does not apply to:

- ✗ Mixtures for "Scientific Research & Development"

Electronic format

Large companies

IT-system

Small/Medium

Basic Application

Companies

SDS software

Product notification Portal?

ECHA

Future European database?

XML format

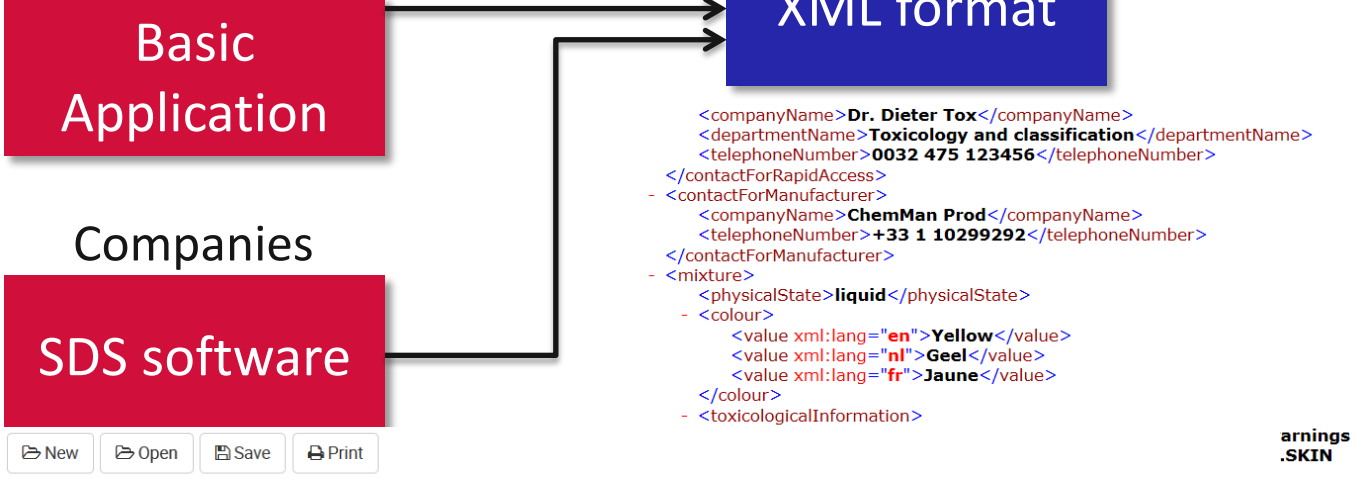
Appointed bodies

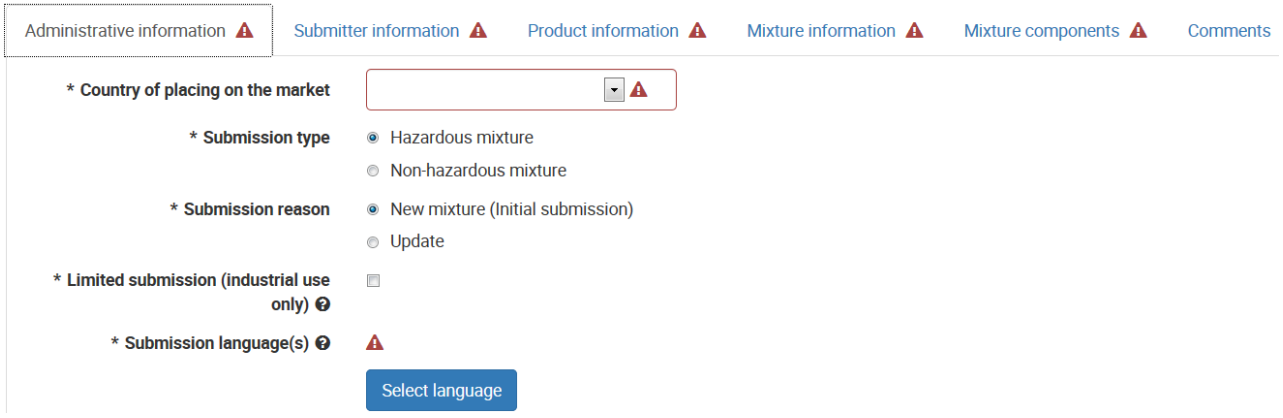
IT-system

- Import module
- XML to PDF

Basic Application

- Used as viewer





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Commission projects

'to support the harmonisation process'

Costs and benefits analysis (2014 study)

Development of tools (EC/Trasys):

1. Electronic format and basic application (2015)
   (to create the electronic format)
2. UFI algorithm and UFI generator (end of 2016)
3. Product Categorisation System (end of 2016)
   (EC: reporting and preventative measures)

Commission projects

'costs and benefits analysis'

Costs and benefits analysis

- For the proposed harmonisation of product information
- For the adoption of a Unique Formula Identifier

Main findings:

✓ All scenarios show overall net savings across the EU

✓ The best estimate indicates savings of around 550 million euro/year (including costs of UFI)

✓ Benefits most clear for larger companies, with larger product portfolio, trading across EU Member States

✓ Net costs for smaller companies, with smaller product portfolio, trading only domestically


Harmonisation!
"ALL FOR ONE - ONE FOR ALL"
DOUGLAS FAIRBANKS
presents
"THE THREE MUSKETEERS"
Adaption, Costuming Research under
EDWARD KNOBLOCK
Direction under
FRED NIBLO
Photography under
ARTHUR EDESON
Poisons Centres
Commission
Industry
Governmental authorities

Implementation of the new legislation

Official publication of CLP Annex VIII: 1 Jan 2017

Transition periods:

- Mixtures for consumer use: 1 Jan 2020
- Mixtures for professional use: 1 Jan 2021
- Mixtures for industrial use: 1 Jan 2024

- The old format can exist till 2025
  (if no updates after 1 Jan 2020)

Coming 3 years Poisons Centres have to prepare!

Coming 3 years Industry has to prepare!

Coming 2 years ECHA has to prepare!

ECHA: provide tools and guidance

'COM/ECHA workshop in January 2017'

Tools (end2017):

- Electronic format and basic application (to create the electronic format);
- UFI algorithm and UFI generator;
- Product Categorisation System (EC: reporting and preventative measures);

  ("In addition, the Commission envisages following up discussions started at CARACAL 20 on possible actions to evaluate information from poison centres with a view to taking preventative action at EU level")

➢ *Development and maintenance of the tools*

Guidance documents:

- On the interpretation of the text of Annex VIII, incl. HD support (end2018);
- On the proper usage of the tools (end2017).

➢ *Development and maintenance of the guidance documents*

Feasability study:

➢ *Possible development of product notification portal (end2017/end2018)*

ECHA: Poison Centres website

Log in » | ECHA

Poison Centres

Advanced search »

Information | Tools | Support

Poisoncentres > Home

3

What is a poison centre?

Poison centres play an important role in the safe use of chemicals. They formulate preventive and curative measures in case of poisoning accidents. They provide medical advice to general consumers and physicians on health emergencies arising from exposure to hazardous chemicals or to other toxic agents.

Poison centres in the EU answer on average 600 000 calls for support each year. Roughly half of the cases are related to accidental exposures involving children.

Under Article 45 of the CLP Regulation, economic operators placing certain hazardous mixtures on the market have to provide information to national appointed bodies. This information is used by poison centres.

This website is established by the European Chemicals Agency to host the tools and format to support the submission of information by companies to the appointed bodies and poison centres.

Quick links

- List of national appointed bodies
- National helpdesks
- ECHA website
- CLP regulation
- DG GROWTH studies

News

More news | RSS

5 April 2016

EU Commission is finalising its proposal for the harmonisation of information according to Art. 45 CLP

This is the result of a long process started in 2010 with the consultation of stakeholders, appointed bodies, poison centres and Member States competent authorities. The regulation is expected to be published in early autumn 2016.

https://poisoncentres.echa.europa.eu/

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Practical consequences

'implementation at NVIC'

Infrastructural changes NVIC:

- Update website to accept upload of product information in xml

  (if ECHA realises portal: probably end of website)
- (Re)build product database to accomodate structured data
- Install automatic control procedures on data/format quality
- Enable presentation of data in the old and the new format

  (possibly link old and new format for product history)
- New export to datawarehouse and new presentation in BI tool

Infrastructural planning NVIC:

- Analysis and design 2018? (depends on final electronic format, PCS)
- Building and testing 2019? (national or international?)
- In production 2020? (1 jan 2020 is the deadline …)

Practical consequences

'implementation by government'

Governmental planning:

- Ministry of Health is responsible for CLP Regulation
- Food and Consumer Product Safety Authority is responsible for communication on CLP

- Discuss roadmap with NVIC
- Discuss roadmap with Industry
- Develop communication plan

- European synchronisation of implementation?

Nog vragen?

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