



EU harmonization of the information for emergency health response (Art. 45 Regulation 1272/2008)

6th BfR-Nutzerkonferenz Produktmeldungen
10 November 2015,
Berlin-Marienfelde

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EU Poison Centres operations

- ✓ EU PCs handle approximately 600,000 calls per annum (close to 1,700 per day);
- ✓ The number of fatalities relating to exposure to chemical goods is around 400 per annum (across EU);
- ✓ The majority of calls relates to consumer/professional products and roughly half of all calls received relates to incidents involving children;
- ✓ In up to 40% of cases poison centres struggle with identification of products which has the potential to lead to over-treatment.





First requirement *Art. 17 Dir 99/45/EC*

"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 "

No details were provided on the format and on the way information should be submitted to the responsible bodies.





Current situation

A considerable variety of notification systems and country specific requirements have been developed in MS; this leads to:

- ✓ unnecessary burden for companies operating in several MS (submission of the same information in different formats).
- ✓ uneven situation between MS with regard to the information available to medical personnel in cases of poisoning incidents





Art. 45 (1 & 4) CLP Regulation

"MS shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market."

"By 20 January 2012 COM 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 EAPCCT, COM may adopt a Regulation adding an Annex to this Regulation "





Stakeholders' consultation

The Commission launched an extensive consultation process with stakeholders (2010-2013):

- ✓ two expert meetings in spring 2010, followed by a workshop held on 24 November 2010 (nearly 80 people PCs, EAPCCT, MSCA and IND);
- ✓ a written consultation was conducted between August 2011 and October 2011 in form of discussion fora and newsgroup;
- ✓ as a result, the Commission review was presented on Jan 2012.





Commission's review art. 45(4)

COM services submitted on January 2012 to CARACAL the review and concluded that it seemed possible to proceed further.

http://ec.europa.eu/enterprise/sectors/chemicals/files/clp/review_art45_4_clp_final_en.pdf

All MS welcomed the report and supported the continuation of the harmonisation process.

Several expert meetings and workshops were organized (from 2012 to 2014).





Costs and benefits analysis

On 2014 a cost-benefit analysis was carried out on the proposed harmonisation and adoption of a UFI.

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

The project included:

- ✓ Two questionnaires x1 Industry, x1 Poison centres (almost 600 replies)
- ✓ Development of a cost model based on results of questionnaires
- ✓ Case study interviews with poison centres based on sliding scale typologies.



Highest data burden

Lowest data burden



More Detailed than SDS
Bespoke tools used
Mandatory submission
Exact composition required

SDS Only
No bespoke tools used
Voluntary submission
Concentration ranges

France	Belgium	Austria	Croatia
Germany	Cyprus	Bulgaria	Denmark
Norway* (observer)	Greece	Czech Republic	Estonia
Portugal	Italy	Finland	Ireland
Spain	Lithuania	Latvia	Romania
		Hungary	Slovenia
		Poland	United Kingdom
		Slovakia	
		Sweden	
Proposal for EU Harmonisation			



Main findings

- ✓ All scenarios show overall net savings across the EU;
- ✓ The best estimate indicates savings of around €550 million per annum (including costs of UFI).
- ✓ However for those companies trading only domestically in MS with lowest data burden there would be a net cost from Harmonisation.
- ✓ Conversely for those companies trading domestically in Member States with 'advanced' systems, they will still see savings under harmonisation.





Recommendations

To minimise costs and maximise benefits:

- ✓ Transitional phase for implementation of UFI;
- ✓ Use of adequate concentration ranges to limit frequent re-submissions;
- ✓ Consider a group UFI for products with similar formulation;
- ✓ Further awareness raising for what is meant by harmonisation;
- ✓ Engage with MS where net costs might occur, to see what additional options can be implemented.





Main elements

The main elements for a possible Commission proposal are presented as follows:

- ✓ **Notification requirement:** *Importers and downstream users will possibly provide information to PCs on all mixtures placed on the market and classified as hazardous (physical and health effects).*
- ✓ **Exemptions** – *Mixtures for R&D, PPORD (REACH) and classified as Gases under pressure and Explosive should be exempted from the notification requirement (extremely unlikely that they will be involved in incidents leading to PCs calls).*





Mixtures for industrial use

- ✓ **Mixtures for industrial use** will possibly be subject to a limited submission requirement: as a minimum dataset, the relevant information in the SDS (Annex II of REACH), provided that additional information on the ingredients is available on request (24h/7d telephone number).
- ✓ **Review** A review of the functioning of this measure, including the limited submission requirements should be carried out after 2021.





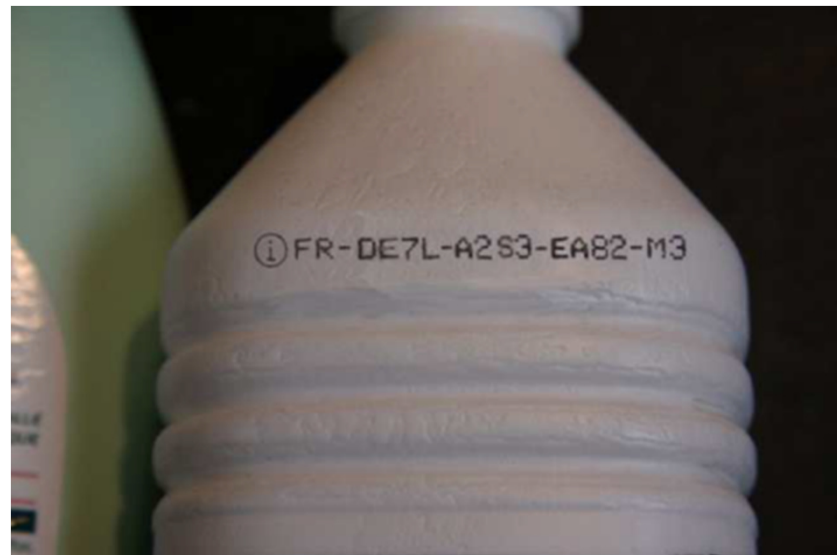
Information to be notified

- ✓ **Concentration ranges/bands** - *The information will possibly be notified in concentration ranges/bands (EAPCCT 2013 Guidelines).*
- ✓ Different **requirements** are provided for hazardous and non-hazardous substances
- ✓ The **nomenclature** will possibly follow Art. 18 CLP. However, names like "perfumes", "fragrances" or "colouring agents" could be used to identify ingredients under certain conditions.



Unique Formula Identifier (UFI)

- ✓ **Unique Formula Identifier (UFI)** - A UFI (a company identifier component) should be printed on labels/packaging and used in the notifications to PCs to facilitate identification of products. A UFI would also facilitate the identification of mixtures in mixtures without disclosure of confidential business information.





Transitional period and categorization

- ✓ **Transitional period** - *Appropriate transitional period should be provided for the date of applicability (e.g. 2019).*
- ✓ **Previous notifications** *should be considered valid* and it will not be necessary to re-notify them, unless a significant change would occur in the meantime. *Sunset date 2025.*
- ✓ **Three steps approach** - *The new measures will be applicable first to consumer mixtures (2019), then to professional mixtures (2020). Applicability to industrial mixtures will follow (2023).*





Ongoing Commission projects

- ✓ ***XML format and basic application*** - delivery date December 2015. (<http://pc-editor.trasys.gr/editor/>)
- ✓ ***UFI generator*** - delivery date end of 2016.
- ✓ ***Product categorisation system*** - delivery date end of 2016





European Commission

New Open Save

Administrative information Submitter information ▲ Product information Mixture information ▲ Mixture components ▲ Comments

*** UFI** ▲ ✕ ▲ ▼
[+ Add UFI](#)

*** Physical state** ▲ ▼

*** Colour** ▲

*** pH** Is not relevant
pH value - Solution concentration %

*** Toxicological information (Section 11 of SDS)** ▲

Classification

*** Hazard category** ▲ ▼ ✕ ▲ ▼
 ✕ ▲ ▼

H314 **P260** **P264** **P280** **P301+P330+P331** **P303+P361+P353** **P363** **P304+P340** **P310** **P321** **P305+P351+P338** **P405** **P501**

[+ Add category](#) [Reset Labelling](#)

Labelling

Signal word [Edit signal word](#)

Pictogram [Edit pictogram](#)
GHS06 GHS05

Hazard statement ✕ ▲ ▼



European
Commission



UFI generator - v1.2

Country :	BE - Belgium	VATN length : 10
VAT identification number :	BE 0998754321	Format : BE0999999999
Formulation code :	1234568	Format : 99999999
<input type="button" value="Generate"/> <input type="button" value="Reset"/>		

UFI: SH5T - SF00 - 211B - P5AS

UFI validator - v1.2

UFI:



Expected outcome and way forward

- ✓ Subject to a political decision in the course of 2015 the Commission services in charge for CLP will prepare a draft proposal for Member States consideration.
- ✓ Adoption by the Commission might follow in the first half of 2016.





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