

# Harmonisation of Information for Poison Centres

## COM review Art. 45(4) CLP Regulation

BfR Nutzekonferenz Produktmeldungen  
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**CLP 2015:  
ACT NOW!**



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# Short history and legal background

## *Article 12 of Directive 88/379/EEC*

- Member States shall appoint the body or bodies responsible for receiving **information on dangerous preparations**, including their chemical composition

## *Article 17 of Directive 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**

## 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 29 August 2011 and 1 October 2011 in form of discussion fora and newsgroup;

as a result, an expert working group on PCs was established.



## **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.

Review weblink

[http://ec.europa.eu/enterprise/sectors/chemicals/files/clp/review\\_art45\\_4\\_clp\\_final\\_en.pdf](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.

While being somewhat more critical on some of the conclusions drawn, industry representatives also supported the harmonisation process.

## Expert WG proposals

- ✓ In the following slides the main elements of the PCs expert working group are reported.
- ✓ Those elements will be presented and discussed in detail at the next REACH and CLP Competent Authorities meeting (CARACAL 13 end Nov).
- ✓ MSCA assessment and final agreement will be instrumental for the preparation of a COM proposal.
- ✓ Therefore, the following slides do not represent the European Commission's view nor the MSCA position.

# Notification and exemptions

✓ **Notification requirement:** *Importers and downstream users should provide information to PCs on all mixtures placed on the market and classified as hazardous.*

✓ **Exemptions** – *Mixtures for R&D and PPORD (REACH) should be exempted from the notification requirement (extremely unlikely that they will be involved in incidents leading to PCs calls). A SDS has to be provided to the recipients of R&D and PPORD mixtures if the REACH requirements are met.*



## Mixtures for industrial use

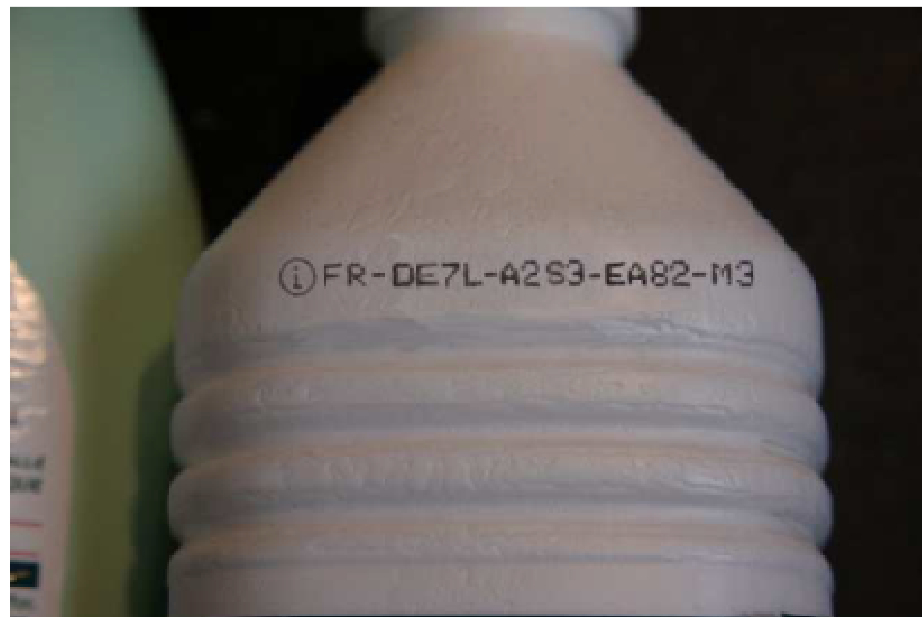
- ✓ **Mixtures for industrial use** should be subject to a limited notification requirement: as a minimum dataset, the relevant information in the SDS (Annex II of REACH), provided that additional information on the ingredients is available on request (24h/7d telephone number),
- ✓ A study programme will **evaluate** the exemptions and whether rapid access (24h/7d availability) to detailed product information was achieved in emergency cases.
- ✓ As a result of this study, a **revision** of the exemptions and limited notification requirement can be considered.

## Information to be notified

- ✓ **Concentration ranges/bands** - The information should be notified in concentration ranges/bands (EAPCCT 2013 Guidelines).
- ✓ Different **requirements** are provided for hazardous and non-hazardous substances
- ✓ The **nomenclature** should follow Art. 18 CLP. However, names like "perfumes", "fragrances" or "colouring agents" and for substances occurring in nature 'essential oil of...' or 'extract of...' could be used to identify ingredients.

# Unique Formula Identifier (UFI)

- ✓ **Unique Formula Identifier (UFI)** - An 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 facilitate the identification of mixtures in mixtures without disclosure of confidential business information.



# Centralised vs regional database

- ✓ **Centralised European versus regional database**
  - Further analysis is still required to decide whether PC notifications should be submitted to a centralised European database or rather to databases in the Member States that would be interconnected and could exchange information between them.
- ✓ A centralised database would require additional resources at EU level, which need approval by the European Parliament and the Council.

## Expected outcome and way forward

- ✓ The final result of the expert working group on PCS will be presented at Caracal 13 for discussion (26 November 2013);
- ✓ MSCA will be invited to discuss and to adopt the expert WG conclusions;
- ✓ MSCA will be also invited to agreed with the presentation of a future COM proposal based on the mentioned conclusions;
- ✓ According to the legislative procedure to be followed the Regulation might be published on 2014/2015.



## Questions on all issues can be sent to

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# CLP 2015: time to update your label!

From June 2015 CLP Regulation will apply to mixtures:  
be ready!

