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The voice of paint, printing ink and artists' colours in Europe

Update on the review of CLP Article 45(4)

Harmonisation of information for Poison Centres

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CLP Article 45(4)

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"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."

* Information on mixtures placed on the market, classified as hazardous on the basis of their **health** or **physical** effects

  - relevant for formulating preventative and curative measures, in particular in the event of emergency health response

A brief history of the review process

- DG ENTR began consultation with EAPCCT, Member States and industry in 2010
  - Series of stakeholder meetings and working groups
- COM report of 20 January 2012 concluded that it is possible to harmonise the information submitted to 'Poison Centres'
  - Included recommendations for main principles and for further analysis to develop a new regulation
- The process is continuing through documents for CARACAL
  - CARACAL 13, November 2013: main elements of possible proposal
  - CARACAL 14, April 2014: working document with preliminary draft for new Annex
  - Written comments invited from Member States and observers

Main elements of the proposal

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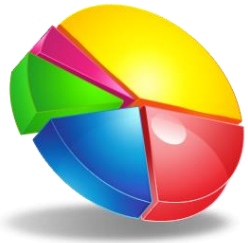
- Notification of **all** mixtures placed on the market which are classified for physical and/or health hazards
  - Exemption for R&D/PPORD mixtures *(provisional, subject to monitoring study and review after 1 or 2 years)*

- Notification using a harmonised dataset and a common electronic (XML) format
  - Notifications to be submitted *before* mixture is placed on the market
- Development of a new EU-wide Product Categorisation System
  - To enable statistical analysis of incidents and identify where risk reduction measures may be needed



Main elements of the proposal (cont'd.)

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- Reporting of mixture **composition**, using exact % or ranges
  - Width of range depends on concentration and hazard of component – varies between 0.05 and 20 % units
  - For consumer/professional products, all (identified) hazardous components to be notified, plus **non-hazardous** components ≥ 1%
  - Component = substance or **mixture-in-mixture** (MIM)
- Limited submission requirement for mixtures for industrial use only
  - Relevant information contained in the SDS, *provided* rapid access to additional information is available **24/7**
  - Subject to monitoring study and review as before
- Unique Formula Identifier (UFI): new unique alphanumeric code to unambiguously link a mixture on the market with its composition

UFI

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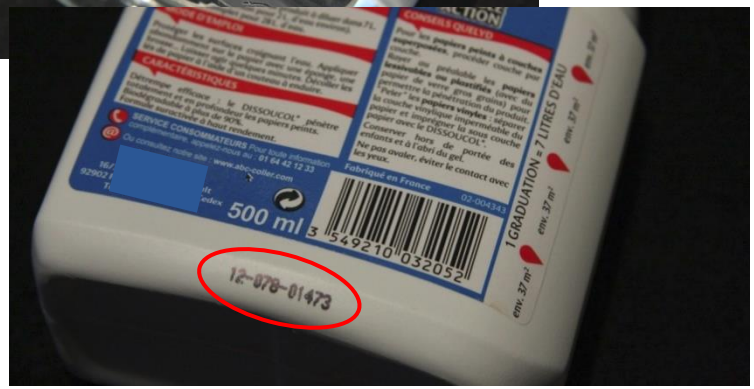

- UFI to be given in notification and affixed/printed on label or packaging (for industrial mixtures, may be provided in SDS instead)
- Notifier will generate own UFI using a free electronic (web) tool

Main elements of the proposal (cont'd.)

- Notifications to be submitted on **national/regional** level – insufficient support from MS for a centralised European database
  - The Commission has published an updated list of appointed bodies
- Submissions to be in an official language of the MS, or **English** should be accepted as an alternative
- **Group submission** possible where several product variants are covered by the same notification
  - Usefulness may be limited because of notification rules
- Transition period longer than 2 years might be considered
- Existing notifications will remain valid, until update necessary

Current status and next steps

- Written comments on working document CA/06/2014 have been submitted to the Commission at the start of May 2014
- The above industry associations submitted joint comments
  - Appeal for phased introduction and/or wider application of reduced notification requirements
  - Extensive comments on the detailed proposal
  - Subsequent requests from industry: more clarity on the obligations of distributors, feedback to suppliers from PCs on incidents
- Mixed views from Member States
  - Some expressed concerns about impact
  - Others reject proposed concessions (e.g. on language or industrial mixtures), or request additional information in notifications

Current status and next steps (cont'd.)

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- The Commission is launching two studies to be completed by October/November 2014:
  - **Assessment of costs and benefits**, for industry in general and SMEs in particular
  - Exchange of information between Poison Centre databases

- Working groups will also be formed to develop two key elements of the proposal:
  - Product Categorisation System
  - XML electronic submission format

  Industry has nominated participants for these groups

And then…

- COM is expected to prepare a further working document for CARACAL in November 2014
- Draft Commission Regulation for voting by REACH Committee in early 2015
- Adoption planned in 2H 2015, with application from 2017 (?)
  - Transition period may be influenced by outcome of studies
- Meanwhile all existing (or new) national requirements remain in place

Conclusions and key messages

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- Industry supports the harmonisation of information for Poison Centres across the EU
- The benefits of harmonisation would however be outweighed by the increased burden for industry (and Poison Centres?) in the current proposals
- Significant time and investment will be needed to adapt to the new requirements
- Industry stakeholders should give input to the Commission's costs/benefits study to help shape the final proposal

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Thank you for your attention

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