I nuovi orientamenti comunitari per l'applicazione dell'Art 45 del CLP

Maristella Rubbiani

National Center for Chemicals

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Content

- Situation before CLP Regulation entered into force
- Legal requirements under the CLP Regulation
- Legal procedure
- Future improvement

Legal Situation before CLP

Directive 1999/45/EC (DPD) - Article 17

- 'MS shall appoint body or bodies responsible for receiving information on preparations considered dangerous on the basis of their health or physical effects
- Appointed bodies shall keep information confidential
- Information may be used for medical purposes, in particular in event of emergency
- Art. 17 does not define which information should be notified
- Resulted in different provisions by MS, different:
  - Procedures
  - Requirements on composition/concentrations
  - Notification formats, tools

CLP Regulation - Article 45

Provisions in Art. 45 of CLP similar to Art. 17 DPD

- MS shall appoint body or bodies responsible for receiving information on mixtures classified as hazardous on the basis of their health or physical effects
- Appointed bodies shall keep information confidential
- Information may be used
  - •For medical purposes, in particular in event of emergency
  - •Where requested by MS, for statistical analysis to improve risk management measures, if needed.

CLP Regulation - Article 45 (cont.ed)

Duties resulting from Article 45(4)

- Assessment of possibility of harmonising information
- Assessment of possibilities to establish a (harmonised) format for submission of information
- No specific reference to a database at EU level
- Consultation with stakeholders, especially EAPCCT
- Legal implementation, if appropriate

Legal framework

Aerosol

Paints

Biocidal products

Plant protection products

CLP/ Dangerous Preparations

REACH

Dangerous Substances

Deter-gents

Cosmetics

Links to other EU legislation

- Regulation on Plant Protection Products (Regulation (EC) 1107/2009)
- Biocidal Product Regulation (Regulation 528 /2013 and Directive 98/8/EC)
- Regulation on Cosmetic Products (Regulation (EC) 1223/2009): a central European database for notification of cosmetic products is already in an advanced stage and the Cosmetic Products Notification Portal (CPNP) is working.
- Details of the data exchange format for both hazardous mixtures and cosmetic products are still under discussion, and where possible, should be aligned.

THE KIND OF INFORMATION REQUIRED BY INDIVIDUAL MEMBER STATES DIFFER SIGNIFICANTLY

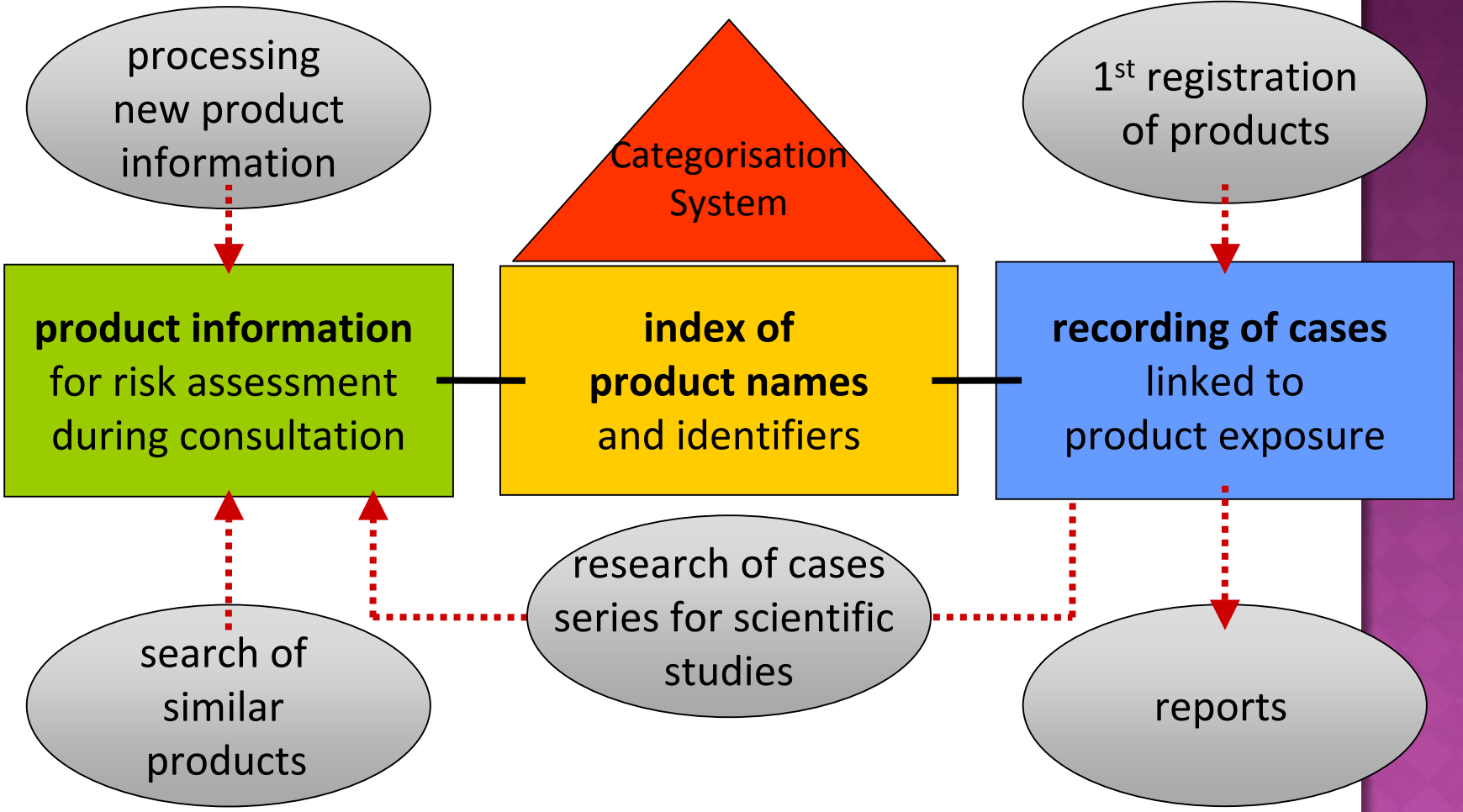
Those differences are caused by different tasks assigned to PCs at Member State level, e.g. use of the information also for market surveillance, enforcement, professional diseases, etc

As a result, a considerable variety of notification systems, data formats and country-specific requirements regarding the requested information have been developed in Member States.

This leads to unnecessary burdens for companies operating in several Member States as they often have to submit the same or similar information in different formats or different information for the same mixture.

It also leads to an uneven situation between Member States with regard to the information available to medical personnel and the general public in cases of poisoning incidents

European Association of Poisons Centres and Clinical Toxicologists



Issues under discussion

- Is it possible and appropriate to harmonise information?

  if yes

- Which information should be harmonised?
- Should there be a common format?

  if yes

- Which format?

Harmonization possible :

- Centralised versus decentralised system for submitting information
- Chemical composition of mixtures
- Designation of ingredients
- Establishment of a data set version identifier (DVI)
- Type of information requested
- Product categorisation system (PCS)
- Unique company identifier (UCI)
- Unique product identifier (UPI)

A possible centralized system

- COM considered that there are many advantages linked to a centralised system, including:
- All information is available in standardised form;
- The information is available for all products Europe-wide even if a certain product is only placed on the market in one or a limited number of EU Member States.
- Consumers can nonetheless buy them when travelling and take them back to their Member State of residence, even if the particular product is not placed on the market there;
- Companies would only need one notification instead of 28 different notifications in a worst-case scenario.

Info to be submitted

- Information about the composition of mixtures;
- Information on the product category;
- Information on the size and type of packaging;
- Information on whether the product is used by consumers and / or by industrial users.

SOME OPERATIVE QUESTIONS:

- Is it necessary and feasible to submit to the PCs the exact composition for all types of mixtures, including non-hazardous ingredients?
- What are the legal constraints?
- What are the expected benefits compared to notification of concentration bands?
- Is there a need for a unique company identifier (UCI) and /or a unique product identifier (UPI) and, if yes, what should they look like?
- Which different procedures are currently used in Member States to receive the requested information?
- Are Member States ready to harmonise these procedures?
- Would a more centralised system, like the Cosmetic Products portal, be a solution but how such a system be managed and financed?

Possible answers

- The information on the ingredients in a mixture can be notified in concentration ranges/bands. The width of such ranges/bands should be defined as a function of the hazards of the substances.
- Non-hazardous ingredients should be notified as well, if they are present above a certain threshold that still needs to be defined.
- The designation of ingredients in mixtures should, where possible, follow the hierarchy as outlined in Article 18 of the CLP Regulation.

Possible options

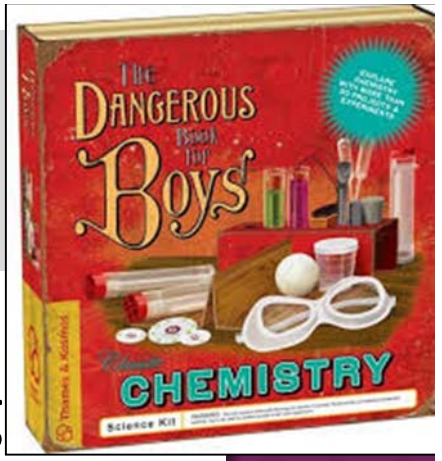
The information contained in the extended SDS as required by Annex II of REACH is considered to be sufficient for PC notifications, but some additional information will be provided :

-composition, including non-hazardous components

-product category

-size and type of the packaging, possibly linked

Unique Product Identification (UPI)



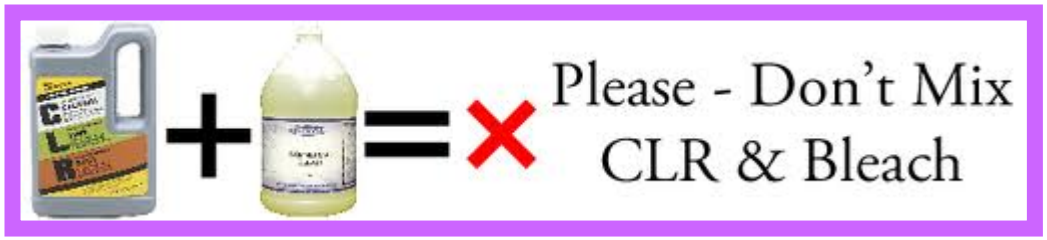
UPI would be a useful tool for solving

Problems identified by PCs or by industry, e.g

- to identify unambiguously the product involved in an incident;
- to determine the composition of mixtures composed of mixtures when suppliers do not
- to disclose all information to downstream users.
- to comparison of exposure data of products in certain categories between European Poisons Centres
- to better combine exposure data of European Poisons Centres into one european annual report

CLP impact on mixtures

It is therefore highly likely that the impact resulting from the application of the CLP also inevitably leads to an increase of the items mentioned in the national databases archives for poison centers



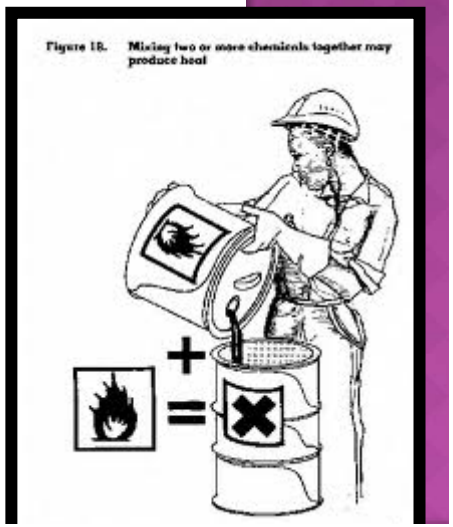
CLP Regulation

- The supplier shall ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required.

- Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling without undue delay.

- Where labelling changes are required the supplier shall ensure that the label is updated within 18 months.

- The supplier of a substance or a mixture within the scope of Regulation 528/2013 or 1207/2009 shall update the label in accordance with those Regulations.



CLP: impact on detergents

Household products	EU	CLP (all cats.)
Laundry detergent (powder)		
Skin irritant	22%	100%
Eye irritant	100%	100%
Laundry detergent (liquid)		
Skin irritant	84%	100%
Eye irritant	100%	100%
Cleaning fluids		
Skin irritant	15%	100%
Eye irritant	65%	100%
Dishwashing liquid		
Skin irritant	88%	100%
Eye irritant	100%	100%

Serious Eye Damage / Eye Irritation: Implications of CLP

Source: AISE

Category of Danger	Concentration limit for classification
Acute oral toxicity 1*	0.025%**
Acute oral toxicity 2*	0.25%
Acute oral toxicity 3*	5%
Acute oral toxicity 4*	25%
STOT 1	1%
STOT 2	10% (but needs SDS on request at 1%)
Skin corrosion 1	5% (becomes Cat 2 skin)
Skin corrosion 1	3% (becomes Cat 1 eye)
Skin corrosion 1	1% (no classification)
Skin irritation 2	10%
Skin or respiratory sensitiser	1% (but needs SDS on request at 0.1%)
CM Cat 1a, 1b	0.1%
R Cat 1a and 1b	0.3% (but needs SDS on request at 0.1%)
CM Cat 2	1% (but needs SDS on request at 0.1%)
R Cat 2	3% (but needs SDS on request at 0.1%)
Aquatic acute 1	0.1% ****
Aquatic chronic 1	0.1% ****
Aquatic chronic 2	1%
Aquatic chronic 3	10%
Aquatic chronic 4	1 %***
* Based on ATE point estimate in Table 3.1.2,	
** Note that if below limit of concern of 0.1% for Cat 1, the legal text implies that substances can be ignored unless it is known to be of concern. Rather vague !	
*** Consider on case-by-case, especially if potential vPvB or PBT.	
**** Note M factor	

-DPD : 20 %

-DPD : 5 %

Note that the text of the CLP Regulation covers this in detail and this is a summary of limit endpoints.

Conclusions

- It is possible and appropriate to harmonise the information to be submitted to PCs;
- There is a the need to develop a European product categorisation system;
- It is possible to develop a common IT format to submit the information and to use XML;

Further work needs to be done with regard to:

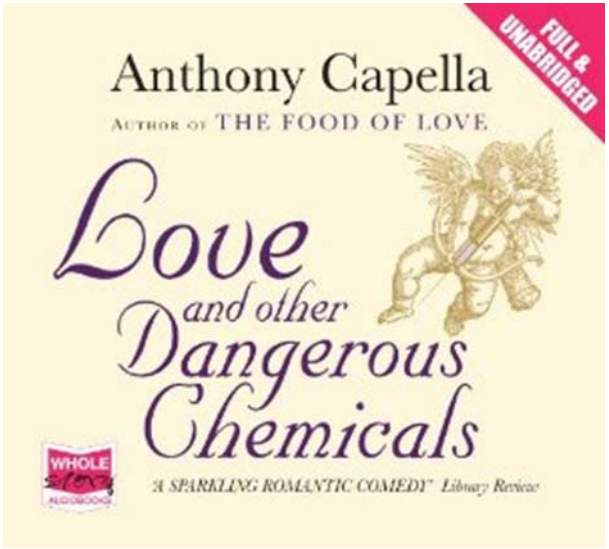
- the level of detail for the information concerning the composition of mixtures;
- the need for a unique company identifier and/or a unique product identifier;
- the need for, and the possibility to establish, a European database for submitting notifications to Pcs.
- Notifications should be possible in all official languages of the country in which a company is marketing its product and/or alternatively in English.

Due to CLP application for mixture (June 2015):

- With the introduction of CLP to mixtures, the number of classified preparations will increas.
- Poisons Centres in EU Member States have to prepare themselves to handle a substantially increased quantity and quality of information on hazardous mixtures and cosmetic products.
- REACH Regulation had improved the toxicological information present on the new SDS.
- Besides a change in hazard classification and hazard communication elements for substances and mixture the label and subsequently the notification of produc information by companies will change.

ISS – Centro Nazionale Sostanze Chimiche
www.preparatipericolosi.iss.it

maristella.rubbiani@iss.it



Thank you for your attention!