EU Poison Centres Webinar

27 May 2014, 9:00am BST
Today’s webinar - aims

v To hear about the current state of play on the changes that are likely to be proposed on the reporting of information to EU poison centres;

v To hear the views of industry on the role of Poison Centres and the likely impacts of the proposed changes;

v To outline the findings of the recent Chemical Watch and National Chemical Emergency Centre survey on the experience of companies and Poison Centres.
Speakers

Roberto Scazzola, Chemicals Unit of DG Enterprise and Industry, European Commission

Doug Leech, Chemical Business Association

Jonathan Gibbard, Ricardo AEA

Chair: Emma Chynoweth, Deputy & News Editor, Chemical Watch
Please submit questions during the webinar using your chat box.

Any unanswered questions can be raised on our Forum following the webinar: http://forum.chemicalwatch.com/
Harmonisation of Information for Poison Centres
COM review Art. 45(4) CLP Regulation

27 May 2014, Brussels

Roberto Scazzola
DG Enterprise and Industry
Chemicals Industry
Table of contents

- Short history and legal background
- Poison Centres Review (Art. 45(4) Classification Labelling and Packaging Regulation, CLP)
- Main elements of the future COM proposal
- Way forward and next steps
"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.
Do we need harmonisation?

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.


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.

2 further expert meetings were organized (Nov 2012 and June 2013)
Main elements of COM proposal

The main elements for a possible COM proposal are presented as follows;

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

Exemptions – Mixtures for R&D and PPORD (REACH) shall 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) - 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. two years after entry into force).
- **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.
Expected outcome and way forward

- Subject to clarification of the open issues, including those related to the costs and benefits study, COM intends to present a draft proposal for CARACAL 16 (November 2014);
- Adoption by the Commission would follow in the second half of 2015.
POISON CENTRES

AN INDUSTRY VIEW OF THE PROPOSED CHANGES
NPIS

- Established for 50 years
- UK Departments of Health approved, and Public Health England commissioned,
  - national service that provides expert advice on all aspects of acute and chronic poisoning.
UK STRUCTURE

NPIS

• Four individual Units
  • Birmingham,
  • Cardiff,
  • Edinburgh and
  • Newcastle
  o Each staffed by Consultant Clinical Toxicologists and Specialists in Poisons Information
  o to provide a national service
UK STRUCTURE

NPIS CUSTOMERS

• A service for frontline NHS staff
  • advice on the diagnosis, treatment and care of patients who have been - or may have been - poisoned, either by accident or intentionally
• Funded mainly through ‘Government Grant in Aid’ from the UK Health Departments
  • But also some contract and research income
• NPIS does not accept enquiries from the public
  • but supports NHS Direct and NHS24 to answer such queries
EU DELIBERATIONS
REGULATION (EC) 1272/2008 - ARTICLE 45(d)

- 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.

- Those measures, designed to amend non-essential elements of this Regulation, by supplementing it,
  - shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3).
CLP REGULATION REVIEW

CARACAL WORKING GROUP

Member states
- Belgium
- Norway
- Greece
- France
- Italy
- Sweden

EU COMMISSION
- DG SANCO
- DG ENVIRONMENT
- DG ENTERPRISE

European Association of Poisons Centres and Clinical Toxicologists (EAPCCT)

Industry
- EU Trade Associations
- Large multinationals

© Copyright CBA 2014  |  www.chemical.org.uk
CONCERNS
PAPER CA/06/2014

• **Increased scope**
  - Expanded to cover industrial mixtures (B2B)
  - Repacking requires notification

• **‘Unique Formula Identifier’ (UFI)**
  - To identify changes in formulations
    - Includes aspects of EU VAT numbers

• **Standardised format of information**
  - Specific information set
    - Prior to placing on the market
  - 24/7 Emergency telephone numbers
INDUSTRIAL MIXTURES

• UK only covers consumer products
  • May need to cover B2B mixtures
    o Regardless of pack size
DISTRIBUTORS

REPACK OBLIGATION

• **Section 0.1.1**
  • Repackers become DSu
    - Need to notify

• **BIG issue for distributors**
  • German system has caveats
    - Importers
    - Repack and relabel
      - Need to notify
    - Repack with no identity change
      - Rely on existing producer notification, if in place
UNIQUE FORMULA IDENTIFIER (UFI)

ALPHANUMERIC CODE

• 4 blocks of 4 digits
  • xxxx-xxxx-xxxx-xxxx
    o EU Vat number
    o Company ID
    o Formulation ID

• Generated by Free IT tool?
  o Printed on each pack
  o SDS for industry

• EU IT projects???

© Copyright CBA 2014 | www.chemical.org.uk
DATA SUBMISSION

CONSUMER

• Identification of:
  • Mixture and submitter
    o UFI
    o Trade Names
    o 24/7 Emergency No
  • Hazards
    o Classification
    o Label elements
    o Toxicological
    o Additional info
      o pH, Colour etc
  • Compositional info
    o Hazardous; and
    o Non-hazardous

INDUSTRIAL

• Reduced submission
  • Utilising SDS
  • Identification of:
    o Mixture and submitter
      o UFI
      o Trade Names
      o 24/7 Emergency No
  • But only if 24/7 No provided
EMERGENCY NUMBER 24/7

ADDITIONAL REQUIREMENT

• Overlap/Duplication
  • Why poison centre number and another?
  • CLP does not require 24/7 number
    o Why do PCs want this?
• Potential confusion and delays
  • Emergency services and customers
    o Which number to use?
• Language
  o Multilingual?
IN SUMMARY

INCREASED BURDEN

- Expanded to B2B mixtures
  - Millions of new submissions
  - Reduced submission
    - Using SDS allowed
      - Need 24/7 emergency number
      - Expensive duplication
      - Potential for confusion and delays
IN SUMMARY

INCREASED BURDEN

• Repacking triggers notification
  • Even if already registered
    o Needs further clarification
      β To reduce burden on both industry and PCs
1. Feedback from NCEC & Chemical Watch survey

2. Practical actions for organisations
Survey findings

Two groups surveyed:

Organisations: 141 respondents

EU Poison Centres: 12 respondents
Survey findings - Organisations

Strong breadth of respondees

Representative view of industry and from a number of different countries – not just EU HQ’d

54% are manufacturers
17% suppliers
6.5% distributors

Chemical Manufacturing: 31.5%
   Manufacturing: 11.1%
   Chemical distribution: 6.5%

Speciality chemicals: 20.4%
   AgroChem: 8.3%
   Adhesives and Solvents: 4.6%
Many organisations are using multiple centres – consistent approach is therefore very important.
Survey findings - Organisations

Experience of using Poison Centres

- Poor: 25%
- Satisfactory: 24%
- Good: 19%
- Excellent: 2%
- No opinion: 30%

SDS admin process

- Poor: 28%
- Satisfactory: 24%
- Good: 23%
- Excellent: 3%
- No opinion: 22%
38% of respondents had experienced variations in the service of the different poison centres

93% of respondents have not been made aware of any calls a Poison Centre has received on their behalf
Survey findings – Administrative concerns

Some countries support an easy submission (like Netherlands, Czech Rep., Germany), others not (like Sweden, Spain, Slovenia)” – Ireland, Greece, Hungary also named as good, Cyprus as poor
Survey findings – Administrative concerns

Wanting 100% of the composition.

Filling in forms that contain the same detail as SDS

Response time
Survey findings – Administrative concerns

No online tools, email and phone difficult, different pricing formats and approaches used
Luxemburg, Malta: no poison centre yet!
Romania, Bulgaria, Czech Rep, Spain, Slovenia: no requirements known, hard to contact. SDSs sent, no confirmation received.
Others: quality satisfactory to good
Survey findings – SDS registration

- Yes: 67%
- No: 33%
Survey findings – Operation

- **36%**: All the poison centres they used operated 24/7
- **25%**: Some of the ones they used operated 24/7
- **38%**: Didn’t know if they operated 24/7
Survey findings – Staffing

Qualifications

• Mixture of doctors, toxicologists, nurses and a few chemists
• Normally doctors in the 5-10 number range per Poison Centre
• Single manning out-of-hours is the norm

9 Doctors  4 Nurses  5 Toxicologists  4 Other
Survey findings – Staffing

>80% Of organisation had no idea about service provision, back-up or staff competencies

25% Of poison centres are using on call staff
Survey findings – Charging

• Variance between €30 and €175
• Possible registration fee on top of this
• No consistency in service delivery for the fee
• Single charging methodology should be rolled out (if charging is to be applied at all)
Practical advice for business

- Engagement
- Budgeting
- Translation
- Data format
- Security
- Operation
- Notification & feedback
- Share
Checklist – do you need to use a PC?

Do you supply a hazardous product for sale into Europe?  
- Yes: ACTION: List numbers on SDS
- No: No action required

Do the countries you sell to have ‘official advisory bodies’?  
- Yes: Contact those advisory bodies and establish the process for ‘registering products’
- No: Provide your own chemical telephone emergency number – Check this meets country requirements

Do you also need to provide your own number for chemical emergency response?  
- Yes: No action required
- No: Review the checklist

Review the checklist
Checklist for your own chemical emergency number

- What hours of operation will this have? (24/7 is best practice)
- Who will answer the phone?
- What advice can they provide?
- What experience and training do response staff have?
- Do you require any foreign language provision?
- What telephone numbers will you use one? In-country?
- How will you cover holidays, illness
Harmonisation - Challenges

- Assurance over operations
- Payment
- Technical capability / availability

Practical action

- Join Poison Centre best practice group [here](#)
- Plan early, make contact early, understand data submission and fees
- More advice in the White Paper [here](#)
Article 45 of CLP:

Appointment of bodies responsible for receiving information relating to emergency health response

1. Member States 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. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24.

2. The information shall not be used for other purposes.

3. The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible.

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.

Those measures, designed to amend non-essential elements of this Regulation, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3).
Thank you for attending

Please give us your feedback by completing our email survey.

A downloadable recording of this presentation (with slides) will be available shortly.

If you have any questions, please contact Lorna (lorna@chemicalwatch.com)