

ECHA preparation for CLP

CLP Conference
Brussels, 17 June 2009

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Topics

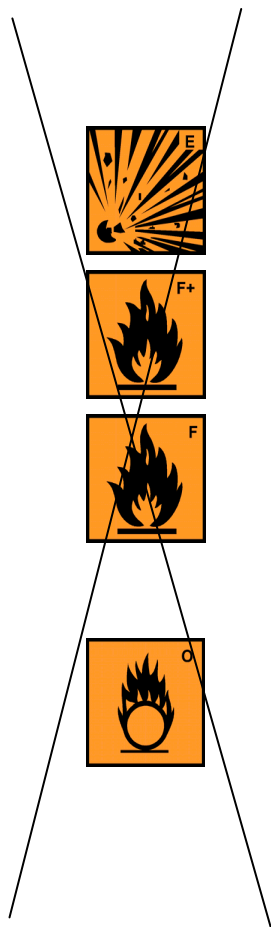
- CLP – what happens and when?
- Responsibilities under CLP
- ECHA's role and status of preparation
 - C&L Harmonisation
 - C&L inventory and notifications
 - Enforcement
 - Alternative names
 - Study on communication of safe use
 - Guidance to industry and MSCAs
 - CLP Communication strategy

CLP Regulation

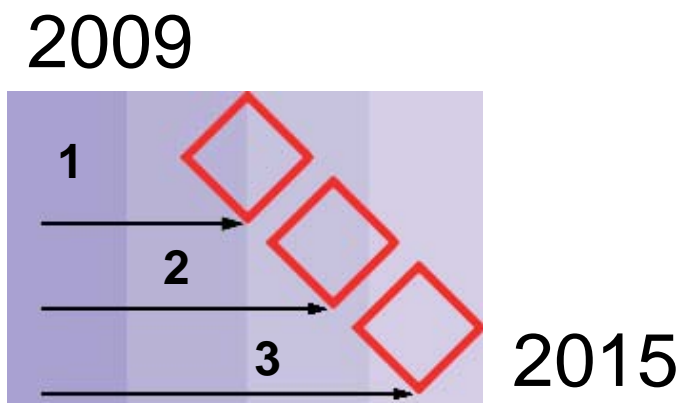


- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging entered into force on 20 January 2009
- Introduces GHS criteria for C&L
- Replaces
 - Directive 67/548/EEC (Dangerous Substances Dir.)
 - Directive 1999/45/EC (Dangerous Preparations Dir.)
 - REACH, Title XI (Classification & Labelling)
- Transitional period 2010 – 2015
 - Both classification systems to be used

What are the time lines?



- 1) CLP entered into force **20 Jan. 2009**.
- 2) Substances to be classified & labelled according CLP by **1 Dec. 2010**
- 3) Mixtures to be classified & labelled according CLP criteria by **1 June 2015**



Main Responsibilities under CLP



- Manufacturers, importers and downstream users shall classify substances and mixtures before placing them on the market
- If a harmonised classification is available, this shall be used
- Suppliers placing a substance or a mixture on the market, shall label and package them in accordance with the classification
- (Group of) manufacturers or importers placing a substance on the market shall notify the Agency

ECHA's role under CLP



- **Process proposals for harmonised C&L (CLH)**
- **Develop and manage the C&L inventory**
- Co-ordinate enforcement activities via Forum
- Receive MS reports on control & enforcement
- Handle requests for use of alternative names
- Carry out a study on communication of safe use
- **Provide guidance to industry**
- **Provide guidance and support to MS-CAs**

C&L Harmonisation (CLH)



- Proposals may be submitted by
 - **MSCAs**: new entries/hazard classes and revisions
 - **Industry** (Manufacturers/Importers, Downstream Users): new entries/hazard classes
- Which types of substances and hazard classes?
 - REACH substances:
 - Carcinogenicity, Mutagenicity, Reproductive toxicity , Respiratory sensitisation
 - Other hazard classes on case-by-case basis if need for Community action
 - Pesticidal & biocidal active substances:
 - All hazard classes
- How many?
 - Estimated 90 proposals per year

CLH: Procedural challenges



- No detailed procedures in the CLP Regulation on how to handle proposals for harmonised C&L
- ECHA has established procedures on
 - Notification of intention
 - Check of accordance with requirements (informal)
 - Process for consultation of parties concerned
 - Process for developing opinion

CLH: Notification of intention



- MSCAs & industry are requested to notify intentions to propose harmonised C&L
 - Webform available
- ECHA checks substance ID
- ECHA consults MSCAs via CIRCA
- ECHA publishes Register of Intentions
 - Allows parties concerned to provide information to dossier submitter
 - Allows parties concerned to prepare for commenting

CLH: Notifications of intention



- Notifications of intention
 - Total No of intentions: 56
 - Proposals submitted: 23
 - Intentions withdrawn: 5
 - Submissions in 2009: 26
 - Submissions in 2010: 3
- Other proposals expected
 - Biocidal active substances: 100-200 (?)
 - Pesticidal active substances: ~200 (?)
 - Other substances: 50-100 (?)
(incl. substances discussed and agreed at TC C&L)

CLH: Preparation of proposals



- Technical dossier in IUCLID 5 format, incl.
 - Substance ID (section 1.1 & 1.2)
 - Classification (section 2.1 & 2.2)
 - Robust Study Summaries (sections 4-7, as relevant for the proposal)
- CLH report contained in IUCLID 5 dossier
 - Specification and rationale of the proposal
 - Summary of relevant information
 - NB! Will be published by ECHA (clear, unambiguous, no confidential information)
 - *New format for CLH report under consultation (partly automatic creation using CSR plug-in)*

CLH: Accordance check (informal)



- Purpose: Check that the dossier seems to contain sufficient data to allow discussion and preparation of opinion by RAC
- Issues to check:
 - Substance ID
 - IUCLID 5 dossier, incl. Robust Study Summaries
 - CLH report
- Prepared by RAC rapporteur, support by ECHA
- If not in accordance, update should be considered by submitter

CLH: Public consultation



- CLH report published for consultation (45 days)
 - Parties concerned
 - Member State Competent Authorities
- ECHA sends to dossier submitter
 - Compiled comments
 - Draft scientific Background Document (based on CLH report)
- Dossier submitter (MSCA or industry)
 - Response to comments
 - Revision of Background Document, if appropriate

CLH: RAC opinion & final adoption



- Risk Assessment Committee will discuss the proposal and form an opinion, based on all available information, documenting the scientific justification in a background document (with support of the ECHA secretariat)
- The RAC opinion and all documents will be submitted to the Commission for adoption by comitology and in accordance with the regulatory procedure with scrutiny (by EP)
- Annex VI is updated and published in OJ
- ECHA publishes Annex VI (the list of harmonised C&L)

CHL: Status of submissions



- 23 C&L dossiers received (9 in 2009, 14 in 2008)
- RAC rapporteur accordance checks finalised for 16 dossiers (most not fully in accordance)
 - 7 dossiers have been re-submitted
 - 1 proposal withdrawn
 - 1 proposal rejected (proposed no classification)
 - 1 re-submission expected soon

Notification of C&L



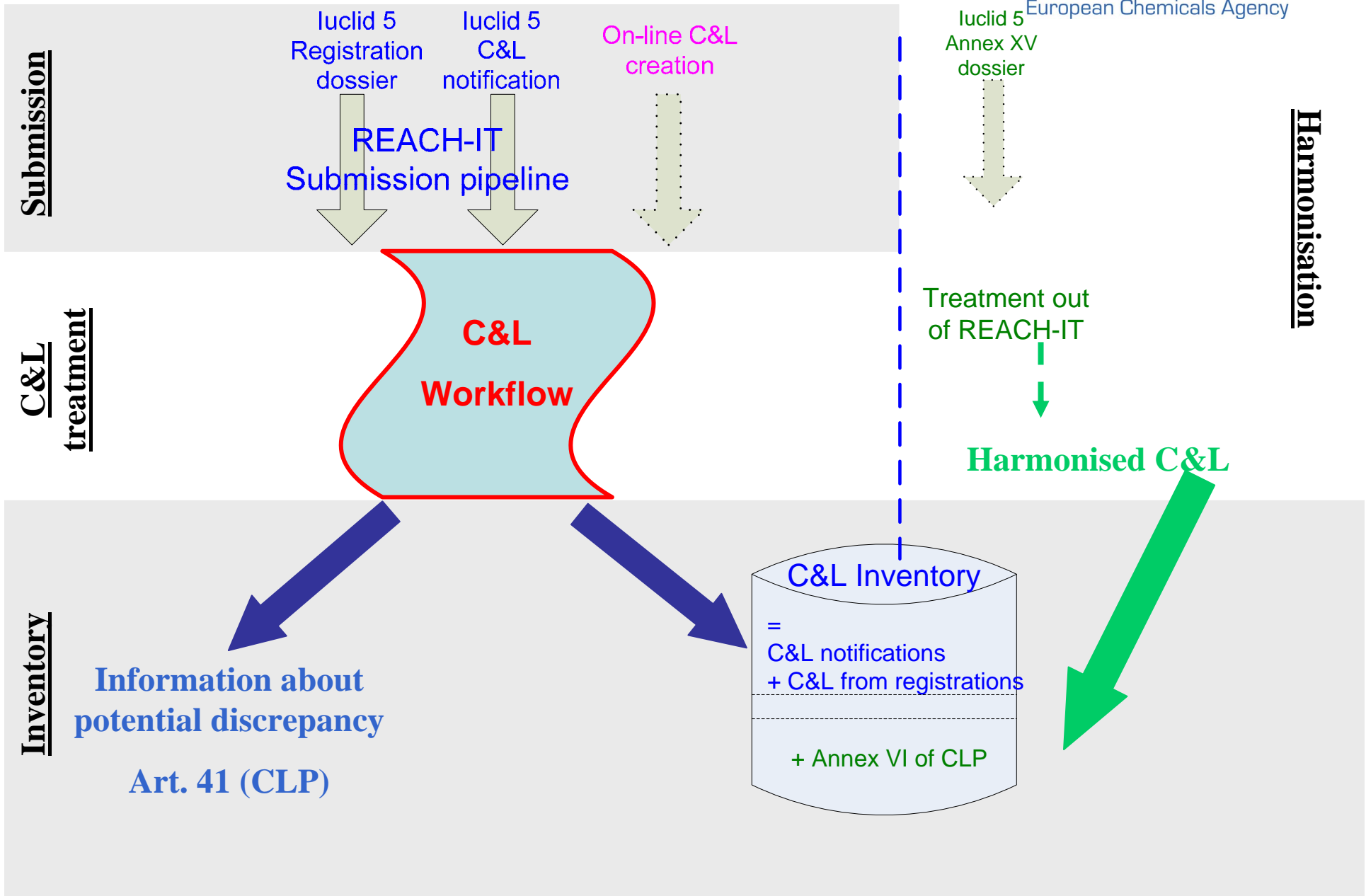
Notification to inventory via REACH-IT application which is currently being designed and built

Elements

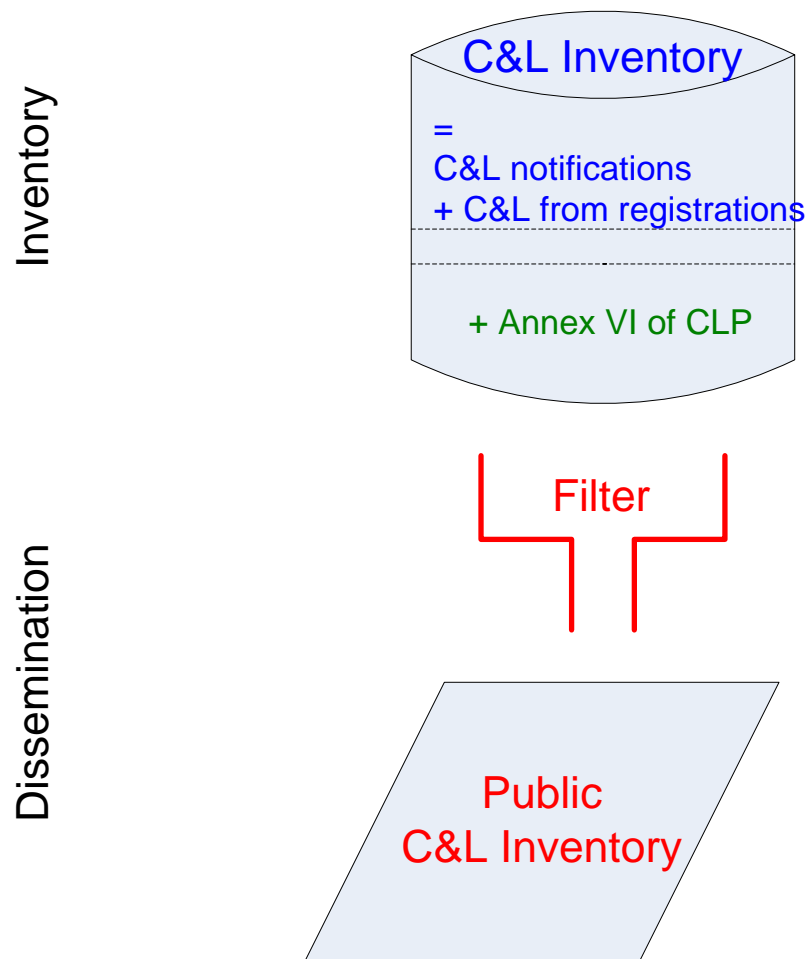
- C&L submission
- C&L workflow
- C&L inventory
- Dissemination web-site

Notification not necessary if the information has already been submitted as part of a REACH registration dossier.

C&L inventory



C&L inventory

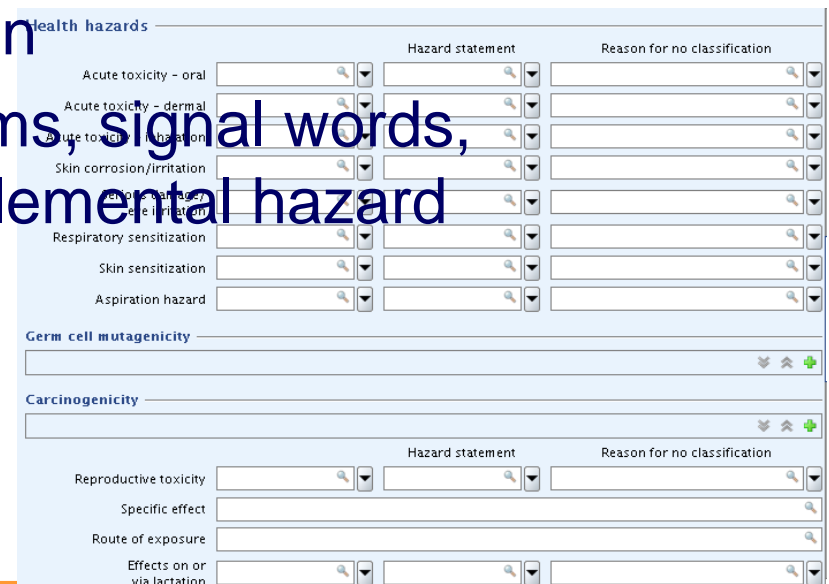


Information to be notified

Article 40

- Identity and contact details
- Identity of the substance(s)
- Classification of the substance(s)
- The reason for “no classification”
- SCLs or M-factors and justification
- Label elements (hazard pictograms, signal words, hazard statements and any supplemental hazard statements)

→ about **200** IUCLID fields for **one** notification!



The screenshot displays a portion of the IUCLID form, specifically the 'Health hazards' section. It features a table with three columns: 'Health hazards', 'Hazard statement', and 'Reason for no classification'. The rows include:

Health hazards	Hazard statement	Reason for no classification
Acute toxicity - oral		
Acute toxicity - dermal		
Acute toxicity - inhalation		
Skin corrosion/irritation		
Respiratory sensitization		
Skin sensitization		
Aspiration hazard		

Below this table are sections for 'Germ cell mutagenicity' and 'Carcinogenicity', each with a search icon and a green plus icon. At the bottom, there is another table with columns for 'Reproductive toxicity', 'Specific effect', 'Route of exposure', and 'Effects on or via lactation', also with search icons.

C&L Notifications: Identified challenges



- Amount of data requested and.... of course substance ID
- Various profiles of notifiers with different needs
- Number of C&L notifications to be submitted
- Submission deadline

C&L Notifications: Various notifier profiles - various needs



Who will notify ?

- The “well-organised” corporate-industry having structured data-base containing all their C&L
- The SME with few C&L to notify
- Research laboratories and institutions

....

C&L notifications: How many?



Last year, about 130 000 C&L notifications expected.... But now:

No tonnage threshold in CLP

+

Experience of pre-registration

=

**A large number of notifications expected
2 millions ? 20 millions ? More ? Less ?**

C&L notifications: What do we do to anticipate the challenges?



- Partnership with Industry to better understand their needs and propose accurate solutions
- Preparation of IT solutions to face those challenges

C&L notification: IT solutions (I)



- Different submission tools to answer all Industry potential needs :
 - ⇒ Creation of C&L using IUCLID 5
 - ⇒ Online creation and submission of C&L **for SME**
 - ⇒ XML creation and Bulk submission for company **with many notifications to submit**

C&L notification: IT solutions (II)



- Considerations on REACH-IT architecture to deal with the expected workload just before the registration deadline
- Pragmatic approach to ease the encoding of data in the notification (eg: aim to reduce number of fields, use of default value if possible...)

Enforcement



Article 46(3)

- Enforcement activities by Member States shall be co-ordinated via the Forum.
- Under preparation, e.g. information session on CLP at last Forum meeting.

Alternative names

Article 24 CLP

- Suppliers may submit a request to the Agency to use an alternative chemical name on the label or in an Safety Data Sheet which refers to a substance meeting certain criteria and contained in a mixture.
- CLP labelling of mixtures applies from 1 June 2015. Nevertheless, in case a supplier chooses to apply CLP in full to mixtures before that date, see CLP Art. 61(2), he would have to submit a corresponding request to the Agency, and not the CA as under DPD, also before that date.

→ ECHA Procedures under preparation

Study on communication of safe use of Chemicals



Article 34 CLP

1. By 20 January 2012, the Agency shall carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. This study shall be carried out in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice.

Hazard communication

- Communication of identified hazards in SDSs and in a condensed and standardised form on labels with

– pictograms, e.g.



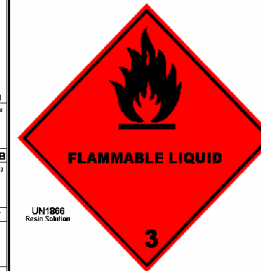
– risk phrases, e.g.

- R36 - Irritating to eyes
- R42 - May cause sensitisation by inhalation

– safety phrases, e.g.

- S15 - Keep away from heat
- S24 - Avoid contact with skin

Bayer		LL 01-1234	
Desmodur N 75 MP/A/X 0215,00 kg B01	2010004158	Made in Germany	
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Bayer AG Geb. D 604, LS LEV SCM SIS D-51368 Leverkusen	215,00 kg 230,50 kg		
1234567890	1234567890		
Barcode		Barcode	
www.bayer.com		www.bayer.com	



Study on communication of safe use: Objectives



- A clear picture of the general public understanding of the new symbols
- An understanding of consumers' attitudes and behaviour - Safe use
- Find out how public information strategies and public information campaigns can help
- A view on whether recommendations for amendments to the present Regulation are advisable or justified?(ART. 34 (2))

Study on communication of safe use: Next steps planned



- Discussion and agreement with the Commission (June 2009)
- Eurobarometer study set up (DG COM + Consultancy, start July 2009)
 - survey protocol ready by the end of 2010
 - Implementation of the survey by using the Eurobarometer survey tool by July 2011
- Development of detailed Vision Documents: desk research/online general survey/educational exercises and focus groups sessions (August 2009)
- Information and feedback about the strategy paper and the vision documents from CARACAL (September 2009)
- Information and feedback about the strategy paper and the vision documents from Risk Communication Network (January 2010)
- Technical questionnaire development (starting Jan 2010)

Guidance to Industry & CAs: Specific for CLP



- Module 1: Basic guidance on procedures
- Module 2: Detailed guidance on C&L
 - Part 1: Physico-chemical properties
 - Part 2: Human health properties
 - Part 3: Environmental properties
 - Part 4: General and specific issues
- Guidance for preparing and submitting proposals for harmonised C&L – CLH dossier (*under revision*)

Guidance to Industry & CAs: REACH Guidance relevant for CLP



- Guidance on registration
- Guidance for downstream users
- Guidance for requirements for substances in articles
- Guidance on data sharing
- Guidance on information requirements and chemical safety assessment

ECHA Helpdesk



- Provides support to national helpdesks via REACHnet
- Internal training
- REACH Helpdesk Correspondents Network (REHCORN) workshop held on 9 - 10 June 2009

REHCORN Workshop on CLP

9-10 June 2009



- Targeted to the national helpdesks which answer questions on the CLP Regulation posed by industry
- Objectives:
 - Training on basic features of CLP and on the transitional provisions
 - Establishment of a network of national helpdesks on CLP
 - Share experiences on dealing with CLP matters and on lessons learnt from helpdesks on REACH

REHCORN Workshop on CLP (2) Highlighting the need to



- Alert unaware suppliers
- Launch an **awareness campaign** in due course
- Provide access to guidance and targeted fact sheets, in particular for SMEs
- Have available sufficient background and technical documents to support the helpdesks
- Provide timely training to the national helpdesks, including train-the-trainers on the relevant IT-tools
- Plan sufficient resources for the hot phase of helpdesk support prior to the notification deadline

REHCORN Workshop on CLP (3)

Therefore...



- CLP is a complex piece of legislation and should NOT be underestimated – it is MORE than a little dinghy that is sailing in the wind shadow of the big flagship REACH...
- Start **NOW!**

Communicating CLP



- ECHA has developed initial plans for an **awareness campaign** to inform about:
 - Obligation for C&L according to CLP
 - Obligation to notify C&L to the Agency
 - IT tools for submission and other practical information available on the ECHA website
- Target group: manufacturers, importers and downstream users in the EU, esp. SMEs and R&D
- Stakeholders are invited to join
 - contact: anja.klauk@echa.europa.eu

Further information



- More information about CLP, how it works and available tools can be found on the website of the European Chemicals Agency in the Classification section at:

http://echa.europa.eu/classification_en.asp