

Un service du Centre de Recherche Public Henri Tudor En partenariat avec le Ministère du Développement durable et des Infrastructures, et le Ministère de l'Economie et du Cammerce extérieur

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General topics

ECHA dissemination portal

We like to draw your attention to the upcoming changes regarding information which will be published on the ECHA website. Manufacturers are strongly encouraged to review their registration dossier and determine if an update is needed with regard to disseminate information and any additional requests for confidentiality.

News

Information on substances notified under Directive 67/548/EEC

Before REACH entered into force, companies notified 'new substances' under Directive 67/548/EEC, the so-called Notification of New Substances (NONS). This notification is as a registration under REACH (Article 24). ECHA will start making information from these notifications available as of May 2012.

This will increase from 78% to almost 100% the number of publishable substances made available on the ECHA website. In order to give NONS registrants required time to adapt the different parts of their dossier to the REACH format, this work will be done step by step (More information here):

- First step (May 2012): classification and labelling of the substance, physicochemical data, data on pathways and fate, results of toxicological and ecotoxicological studies, the DNEL and PNEC (if available) and the guidance on safe use.
- Second step (Autumn 2012): ECHA will start adding the Safety Data Sheet (SDS) related information (e.g. name of firm and the registration number)
- Third step: the remainder of the information according to Article 119 of the REACH Regulation will be published after the 2013 registration deadline.
 - dissemination of information from Safety Data Sheets

More information on chemical substances usually found in the Safety Data Sheet (SDS) will be made publicly available on ECHA's website from autumn 2012. ECHA publishes a <u>Q&A</u> <u>document</u> to provide details in advance on the dissemination and new confidentiality claims of such information in IUCLID 5.4, and encourages registrants to familiarise themselves with the upcoming changes. More information in <u>ECHA's News alert</u> and in the document "<u>Dissemination and confidentiality claims of SDS information in IUCLID 5.4</u>".

FAQs recently updated

You will find the whole FAQs in the section "<u>support</u>" of ECHA's website. ECHA database of Frequently Asked Questions contains questions and answers on issues, which are of general interest for the stakeholders. The FAQs are compiled on the basis of questions received by the ECHA and the national helpdesks in the Member States. The last updates concern REACH FAQs (version 4.4 of 3/07/2012) and CLP FAQs (version 3.0 of 3/07/2012).

Lunch Meetings - Understanding REACH&CLP key points and issues

The presentations of the two seminars (in French and German) on "Understanding REACH&CLP key issues and challenges", organized by the Chamber of Crafts and the REACH&CLP Helpdesk Luxembourg, are now available in our website – section <u>Documentation</u>.



To subscribe / unsubscribe: www.reach.lu/contact or www.clp.lu/contact or by email.

Save the date!

All the information sessions of the REACH&CLP Helpdesk Luxembourg are free on prior registration. For more information, consult our flyer on upcoming events 2012.

Presentations from ECHA's <u>Stakeholder's Day</u> are now available.

Presentation of webinars already organized by ECHA are available under the section « <u>webinars</u> » on ECHA website where you can also find the list of upcoming webinar starting from September



REACH Excel Tool

REACH&CLP Helpdesk Luxembourg offers an update of its optimized « <u>REACH Excel</u> <u>Tool</u> ». You can download it, free of charge, in French or in German in our website.

ECHA publishes a practical guide for downstream users on exposure scenarios

This <u>new practical guide</u> helps downstream user to handle exposure scenarios that they receive with a safety datasheet. It provides an overview of the main duties of downstream users, illustrative examples and tips for checking whether your uses and use conditions of a chemical substance are covered by exposure scenarios provided by suppliers with the safety datasheet. Further information can be found in <u>ECHA's Press Release</u> and <u>ECHA's downstream user webpage</u>

REACH (Registration, Evaluation, Authorisation and restrictions of CHemicals)

Registration : update of ECHA's dossier submission tools

 <u>IUCLID 5.4</u>: it includes additional fields for reporting exposure, PBT (Persistent, Bioaccumulative and Toxic chemicals) and human hazard assessment data as well as other new functionalities (folder structure, bulk user creation).



- <u>Chesar 2.0</u>: this update increases the stability of CHESAR. Furthermore, the new version has a redesigned user interface, more transparency in determining the scope of the required exposure assessment, a simplified risk characterization and an updated version of the Targeted Risk Assessment (TRA) developed by ECETOC. The possibilities to import and export complete chemical safety assessments (CSAs) or CSA building blocks have also been extended.
- <u>REACH-IT</u>: the new release of REACH-IT, now ready for use, only accepts dossiers created with IUCLID 5.4. The updated tools that support industry in submitting such dossiers IUCLID plug-ins and manuals are also available.

More details in ECHA's news Alert on <u>IUCLID 5.4</u>, <u>Chesar 2.0</u> and <u>REACH-IT</u>.

Evaluation : several <u>public consultations</u> on testing to avoid unnecessary animal testing; deadlines: 19 July, 2 August and 9 August 2012.

Authorization : Candidate List updated and 4th recommandation for Annex XIV

New SVHC included in the Candidate List

Thirteen new substances of very high concern (SVHC) have been identified based on their CMR (carcinogenic, mutagenic, toxic to reproduction) properties and were added to the Candidate List. <u>More information here</u>.

• Public consultation on inclusion of ten new substances in the Annex XIV

ECHA launched a <u>public consultation</u> on its draft recommendation of ten new priority substances to be included in the Authorisation List, for its 4th recommendation to the Commission: formaldehyde, oligomeric reaction products with aniline (technical MDA), arsenic acid, dichromium tris(chromate), strontium chromate, potassium hydroxyoctaoxodizincatedichromate, pentazinc chromate octahydroxide, bis(2-methoxyethyl) ether (diglyme), N,N-dimethylacetamide (DMAC), 1,2-dichloroethane (EDC), 2,2'-dichloro-4,4'methylenedianiline (MOCA). Interested parties are invited to submit comments before 19 September 2012, using the web forms available on ECHA's website. Further information can be found in ECHA's Press release.

Restrictions : Annex XVII updated and public consultations on going

- Annexe XVII updated : the <u>Commission Regulation (EU) No 412/2012</u> of 15 May 2012, amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), added Dimethylfumarate (DMF) to this Annex.
- On going public consultations
- <u>Public consultation</u> on SEAC's (Socio-economic assessment Committee) draft opinion on the restriction of the four phthalates DEHP, DBP, BBP, and DIBP in consumer articles (see also <u>ECHA's Press release</u>); deadline: 3 September 2012.
- <u>Public consultation</u> on the proposed restriction of 1,4-dichlorobenzene in air fresheners and toilet blocks (see also <u>ECHA's</u> <u>Press release</u>); deadline: 19 December 2012, comments preferably until 3rd September 2012.
- on the proposal for <u>Chrome VI restriction in leather articles</u>, deadline : 16/09/2012.

For further information, please visit our website

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CLP (Classification, Labelling and Packaging of substances and mixtures)

ECHA publishes the first report on the CMR substances registered or notified after 2010

The report "*CMR substances from Annex VI of the CLP Regulation which are registered under REACH and/or notified under CLP*", published by ECHA (based information available at the Agency in April 2012) is also the first opportunity to take a look at the CMR - carcinogenic, mutagenic or toxic to reproduction - substances which have now been registered and/or notified. More information can be found <u>here</u>.

CLP: harmonised classifications and labellings

The CLH (Classification Labelling Harmonisation) process is an active process and several discussions are on-going around this topic. The last news are the following:

- Registry of intention of Member States: two new substances have been added in June 2012. You can consult the <u>registry of</u> <u>intentions</u>, which currently contains 43 substances on the ECHA's website.
- ECHA launches new public consultations on reproductive toxicity of <u>epoxiconazole</u> (CE number: 406-850-2) as well as on new CLH proposals for five biocides/pesticides (tricalcium diphosphide, flonicamid, octanoic acid, nonanoic acid and decanoic acid) and nitric acid. The Agency invites the parties concerned to comment within the given deadlines (23/07/2012 and 6/08/2012).
- The Committee for Risk Assessment (RAC) has adopted five scientific opinions on proposals for harmonised classification and labelling across Europe for: P-tert-butylphenol, Acrolein, Fluazinam, Dioctyltin bis(2-ethylhexyl mercaptoacetate), Ethylbenzene.

We invite you to regularly check the page "addressing chemicals of concern" of ECHA's website, where you can follow the latest consultations related to the different procedures.

For further information, please visit our website

AGENDA

This section is updated regularly on our website, consult it at www.reach.lu/agenda.

National events

October 2012	Information session on Downstream User obligations under REACH and CLP (intermediate public)
(date to be	and REACH&CLP Coffee on "the "Safety Data Sheets and Exposure Scenario for Experts" (expert
confirmed)	audience) at CRP Henri Tudor (L-Kirchberg).

International events

06/09/2012	ECHA webinar: "Dissemination and Confidentiality Claims". More information here.
1 - 3/10/2012	ECHA proposes two courses: <u>"Overall understanding of the authorisation application procedure"</u> et <u>"Practical aspects of how to prepare an Analysis of Alternatives and Socio-Economic Analysis"</u> . Registration deadline: 27 August 2012

You will find presentations from the events organized by ECHA in <u>section "events"</u> of ECHA's website.

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