Newsletter

Volume 12, No. 1S, March 2012

SPECIAL EDITION

ChemCon Europe 2012

SCC GmbH is an active participant at this year's ChemCon Europe 2012 international conference on chemical control legislation and trade aspects, which is being held in Madrid from 5 – 9 March 2012 in Madrid. This global platform brings together more than 200 experts representing companies, authorities and international organizations from over 25 countries. Presentations will focus on the field of international chemical legislation all over the world, including REACH, GHS and country-specific information on inventories, labeling requirements, etc.

Many experts are expected to join in this event, representing companies, authorities and international organizations. SCC is proud to be a part of this exhibition!

Feel free to stop by SCC's stand during ChemCon Europe. Dr. Charlotte Krone, Senior Manager Regulatory Affairs, will be available to discuss your specific needs regarding REACH, GHS and other country-specific registration requirements.

In this special issue of the SCC Newsletter, you will find the latest news regarding REACH.

Comprehensive information regarding the ChemCon will be handled in the next edition of the SCC Newsletter, which will be available at the end of March 2012..

In this issue:

Chemicals / REACH / Consumer Products p. 2

Newsletter

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CHEMICALS, REACH, CONSUMER PRODUCTS

Authorizations under REACH

In February 2012, Annex XIV to the REACH Regulation[1] was updated by including eight new substances. With the publication of these inclusions, the respective application dates for authorization as well as the last possible date (sunset date) for which the placement of Annex XIV substances on the market without authorization were also fixed.

The new substances subject to authorization are:

1. Diisobutyl phthalate (DIBP)
2. Diarsenic trioxide
3. Diarsenic pentaoxide
4. Lead chromate
5. Lead sulfochromate yellow (C.I. Pigment Yellow 34)
6. Lead chromate molybdate sulphate red (C.I. Pigment Red 104)
7. Tris (2-chloroethyl) phosphate (TCEP)
8. 2,4-Dinitrotoluene (2,4-DNT)

The earliest application date for DIBP is 21 August 2013, with the earliest sunset date set for 21 February 2015.

With the authorization process under REACH, risks arising from substances of very high concern (SVHC) will be properly controlled. SVHC will be replaced step-by-step by substances with fewer risks, if economically and technically feasible.

The authorization process already starts with the identification of SVHC substances in manufactured products and publication on the Candidate List. This triggers immediate action with regard to communication in the supply chain as well as notification requirements for candidate substances in products. Once a substance is listed on the Candidate List it will remain permanently on that list and the respective requirements will permanently apply. For interested parties it is therefore highly recommended to make use of the commenting phase before a substance is included the Candidate List.

[1] Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Online Inquiries

Under REACH (Regulation 1907/2006/EC) every potential registrant of a non-phase-in substance (or a phase-in substance that has not been pre-registered) has to inquire at ECHA whether a registration has been previously submitted for the same substance. In this context before submitting an updated registration dossier, e.g. due to a tonnage band increase, the registrant must inform ECHA (via an inquiry) about the additional information required for the next tonnage level (Article 12(2)).

In general, there are two options for preparing an inquiry dossier: either directly online in the REACH-IT system or as a full inquiry IUCLID dossier that will be submitted through REACH-IT. In the case of an inquiry for tonnage band increase, the direct online preparation in REACH-IT may be more efficient (assuming that a complete registration dossier is available for which the tonnage band update is to be made) as crucial parts of this update, in particular that the substance identity including the analytical information, refers to a previously successful registration and does not have to be compiled again.

ECHA Feedback: evaluation of intermediate dossiers according to Art. 18 REACH

SCC has received feedback from an ECHA evaluation of an intermediate dossier according to Art. 18 REACH. ECHA asks for significantly more information than usually submitted, such as detailed documentation of downstream user communication and a detailed technical description of the strictly controlled conditions as outlined in the respective ECHA guidance documents. As intermediates are under focus, full dossiers were expected by ECHA for many of these substances, meaning that similar/identical feedback can be expected for other substances in the near future.

If you have already filed such a dossier, you may consider updating your dossier. Alternatively, at least start collecting the required information (if not already on hand) and initiating the completion of the respective ECHA template, in order to be prepared for such requests.

SCC can provide you with support for such matters – give us a call!

2013 Intentions

At the end of 2011, ECHA initiated a survey based on pre-registration information and contacted companies to get a more accurate picture of all the phase-in substances to be registered by the 2013 deadline.

The preliminary results of the survey published reveal a list of 2300 substances that will be registered for the first time by the next deadline. ECHA will update the list on a monthly basis and would like it to be as complete as possible.

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The list of substances will also be useful for downstream users to know whether the substance under use has already been registered or is expected to be registered by 2013. However, as the list is not providing information about the uses covered by the lead, downstream users are still advised to contact their suppliers and to communicate their specific uses to make sure they will be covered in the chemical safety assessment and exposure scenarios associated with a registration.

Details can be found on the ECHA website http://www.echa.europa.eu/ under the section "Information on Chemicals".

Joint submission approach: Relevancy for Phase-in and non Phase in

As recently confirmed by the ECHA Helpdesk, the joint submission approach equally applies to phase-in and non phase-in substances. In general, multiple registrants of the same substance shall submit jointly certain information and thus enable a successful link in the registration system, helping to reduce costs as well as testing on vertebrate animals. The REACH Regulation (Articles 11 and 19) does not distinguish between phase-in and non-phase-in substances.

The dossiers of substances that have already been registered can easily be updated by the first registrant. Acting as lead, the dossier needs to updated as joint submission and marked as “change of tonnage band". For detailed technical support (REACH-IT and IUCLID5) please refer to ECHA Practical guide No. 9 (How to do a registration as a member of a joint submission) as well as to the actual REACH FAQs, Section 10 on the ECHA Homepage. If you need support by SCC, please does not hesitate to contact us.

C+L inventory released

ECHA has released on its website the classification & labelling (C&L) inventory on notified and registered substances (REACH registrations and CLP notifications) received from manufacturers and importers. Besides a list of harmonised classifications (cf. table 3.1 and 3.2 of Annex VI, CLP regulation) the inventory provides information from industry on their self-classification of chemicals and presents how companies have classified the same substance differently. For each classification of a substance the number of registrants is presented. In addition, classifications made by the lead registrant under REACH are marked with a tick. Important to note is, that proposals for none classification (even if proposed by the majority of companies/data holders) is not given. For downstream users it is thus possible to decide on the most reliable classification. A number of options are available for searching this inventory, based on both the substance identity and its classification. Unfortunately, substances for which no classification is proposed are not listed in the inventory. These substances have to be checked via the ECHA dissemination website showing registered substances. The inventory can be accessed on the ECHA website under the section "Information on Chemicals".

For more information, contact Dr. Werner Köhl at werner.koehl@scc-gmbh.de.

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