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Sustainability Support Services (Europe) AB

One Stop for 'ACCREDITED' Chemical Regulatory Compliance Services & Solutions

EDITORIAL

Sustainability Support Services (Europe) AB is pleased to share the first issue of its Newsletter in 2015 on "Global Chemical Regulatory Updates". The focus of this Newsletter is to provide important updates to the client companies of SSS with important regulatory developments concerning chemicals, globally. Companies wishing to seek more details on any news item of their interest may please write to REACH Support.

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Important regulatory developments impacting non-European companies

Companies exporting to South Korea need to comply with the chemical regulation known as K-REACH

The Act on the Registration and Evaluation of Chemicals (known as Korea REACH due to its similarity to the EU REACH regulation) came into effect on Jan 1, 2015. The Korean Ministry of Environment (MoE) is responsible for the registration and evaluation of chemical substance under this Act. The purpose of this Act is to protect public health and the environment through the following provisions:

- Registration of chemical Substances
- Screening of hazardous chemical substances

- Hazard and risk assessment of products containing chemical substances and hazardous substances
- Sharing information of chemical substance

Similar to EU REACH, K-REACH also requires the **joint submission of registrations.** The data pertaining to the physic-chemical, eco-toxicological and toxicological properties shall be submitted by the lead registrant and jointly shared by the other registrants. Joint members need to submit their own information in their respective individual dossier. When a new member intends to join the joint submission, the inquiry can be sent to MoE about the previous registration data of the same chemical and then the new member follows the further process and joins the joint submission.

K-REACH also sets out requirements for companies to report the volume and uses of substances they manufacture/import ("annual report") and notify products containing hazardous chemicals substances ("product notification"). Foreign manufacturers who export chemical substances to Korea may appoint a Korea-based only representative to submit annual report or registrations or product notifications. Deadlines of registration for designated existing substances are to be set by MoE.

- The 1st list: 2 years from the publication date
- The 2nd list: 5 years from the publication date
- The 3rd list: 8 years from the publication date

SSS is following the developments related to the REACH regulation since certain updates are expected in the near future. SSS is also working towards providing the OR services for non-Korean companies to comply with K-REACH.

Biocidal Product Regulation (BPR): Active Substances Supplier's List also known as Article 95 list updated

Companies exporting chemicals to European markets that find applications exclusively for biocidal applications shall have to comply with the Biocidal Product Regulation (BPR). The BPR regulation has come into effect from **1 September 2013** and concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

Suppliers of Active Substances having biocidal applications shall have to get listed on the Active Substances Supplier's List also known as Article 95 list. There is a provision for non-European companies to get this compliance activity done through a "European Representative" (ER) if they do not want their importer to be involved in this activity to safeguard their business interest and confidential business information (CBI).

Certain Indian companies have already begun compliance and have been listed in the Article 95 list within the BPR regulation through their European representative. It is important to remember that the deadline for getting listed in the Article 95 list is the 1st Sept' 2015. Beyond this date, the non-listed companies shall not be able to export to the European markets till they complete the compliance procedure and the European Chemicals Agency (ECHA) informs them of their successful inclusion in the Article 95 list.

In addition, there could be other NEW active substances of companies having biocidal applications for which a different compliance process within the BPR regulation shall have to be required. In addition,

depending upon the European country to which your company exports the biocides; there could be a requirement for National and Union Authorization.

The regulatory team of Sustainability Support Services, SSS, has been following all the developments and compliance procedures related to BPR and would like to inform the companies that getting listed on the Article 95 list is a time consuming process and shall not be as quick as the REACH Late Pre-registration. SSS has the technical expertise to help companies with this listing and would be happy to help the companies interested in doing so.

Other Updates

ECHA's annual evaluation report published

A significant number of the Registration dossiers examined by ECHA were found to still require improvements. In majority of the cases, ECHA accepted the testing proposals included by the registrants in their REACH Registration dossiers. In only one case, the testing proposal was rejected. Thus, companies need to be aware that if for their registered substance(s), any testing proposal has been approved then the lead registrant shall request them for their share of the additional testing cost.

REACH restrictions updated for Polyaromatic Hydrocarbons (PAHs) and phthalates

Polyaromatic Hydrocarbons (PAHs) and phthalates are the chemicals that are frequently used to manufacture various articles like toys, plastics, electrical devices, other skin contact articles, etc. ECHA has reasons to believe that restrictions as opposed to authorisations, may be necessary for the phthalates since most of the articles containing them have been produced outside the EU. As such, they are unaffected by any authorisations, which only apply to chemicals and articles manufactured in the EU. In principle, it is felt that such a restriction would create a level playing field for article manufacturers within and outside Europe. However, Member State enforcement authorities would face "a major challenge", particularly with respect to imported articles from China, India, other Asian countries and Latin America.

The agency notice on phthalates marks the first time that it has been required to prepare a restriction dossier under Article 69. This is because the other substances subject to authorisation are either not used in articles, or have not yet reached their sunset date. However, ECHA says it is assessing a number of substances on the authorisation list for possible future restriction proposals.

ECHA changes the requirements for reproductive toxicity testing effective 13 March 2015

The Extended One-Generation Reproductive Toxicity Study (EOGRTS) is a new test method developed to assess the reproductive toxicity of chemical substances. This test method was adopted by the Organisation for Economic Cooperation and Development (OECD) in July 2011. EOGRTS is a modular test method, where breeding and assessment of a second filial (F2) generation and testing for developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) constitute distinct and independent modules.

EOGRTS is considered to offer a number of advantages in comparison to the two-generation reproductive toxicity study. It assesses a greater number of animals of the first filial (F1) generation and addresses additional parameters, thus improving the sensitivity and level of information that can be

obtained from the test. Furthermore, as breeding of the F2 generation is not part of the basic test design, a significant reduction in the number of animals used is achieved if this design is used.

The EOGRTS should become the preferred test method to address the standard information requirement defined in Annexes IX and X to the REACH Regulation (EC) No 1907/2006 instead of the two-generation reproductive toxicity study.

It is important to note that this requirement shall apply to the registration of chemicals within REACH in volumes exceeding 100 tons per annum (and in exceptional cases; below 100 tons per annum if the chemical poses hazards for reproduction or developmental toxicity).

SSS professional attends ECHA meeting related to "chemical safety report and safety assessment"

As part of the regular meetings organized by the ECHA group on chemical safety reporting and safety assessments, a meeting was organized in the ECHA office in Helsinki, Finland on the 25th Feb' 2015. The meeting was related to upgradation of the CHESAR tool offering a better possibility to use special environmental release category (SpERC) which is a better and more practical option as compared to environmental release category (ERC). A senior professional of SSS attended this meeting resulting in knowledge enhancement.

SSS professional to attend a meeting on "facts about QSAR models and read across"

A meeting is being organized by the Istituto di Ricerche Farmacologiche Mario Negri, IRCCS on the 29th April'2015 in Milan, Italy to discuss the applicability of generating results using Non-testing methods for mutagenicity, carcinogenicity and developmental toxicity; in addition to logP, BCF and fish acute toxicity. This meeting shall also deliberate steps to improve the use of non-testing methods & needs and possibilities of the use of in silico methods. Considering the relevance of the meeting, SSS has delegated one of its senior professional, well-versed with QSAR to participate in the meeting for knowledge and skill enhancement.