

Workshop on ‘Developments in Chemical Regulations (EU, ASIA & UK-after Brexit)’

Chennai (26.11.2019) | Mumbai (28.11.2019)

EVENT SUMMARY

INTRODUCTION

SSS Europe organized two back-to-back events on ‘Developments in Chemical Regulations (EU, ASIA & UK-after Brexit)’ on 26th and 28th November, 2019, at Chennai and Mumbai respectively.

The workshops were organized in collaboration with the two esteemed industry associations, namely, **CHEMEXCIL** (for both the locations) and the **Chemical Industry Association (CIA)**, Chennai (for Chennai alone). The main focus was on the recent developments in various global Chemical Regulations with specific focus on K-REACH regulation from South Korea, EU’s REACH regulation, Turkey REACH, Taiwan regulation and implications of Brexit with upcoming UK REACH regulation.

INAUGURAL SESSION

The workshop began with the welcome address from **Mr. Shisher Kumra, Executive Director, SSS Europe**. Mr. Kumra welcomed all and also thanked the co-partners, CIA and CHEMEXCIL, for their co-operation. Mr. Kumra also gave a brief overview of the SSS activities and the program schedule for the day.

At the Chennai event, **Mr. Ilanahai**, President of Chemical Industry Association, Chennai was present for the inaugural session, while **Mr. Prafulla Walhe**, Deputy Director, CHEMEXCIL, was present at Chennai as well as Mumbai.



Inaugural session at Chennai

During his address, Mr. Walhe informed about the recent circular from the Ministry of Commerce about **Market Access Initiative (MAI) Scheme**, wherein all those companies registering their substances after **7th January, 2019**, would be eligible for a **reimbursement of 50%** of the ECHA fee as well as the letter of access (LoA) cost from Government of India, with **Rs. 2 Cr per year per company** being the maximum limit.

As the key note speaker at Chennai, **Mr. Ilanahai** urged the participating companies to be prepared for the compliance challenges that lay ahead, and also encouraged them to take advantage of such informative workshops to learn about the regulations and to overcome the challenges.

TECHNICAL SESSIONS

The technical sessions were presented by **Mr. Shisher Kumra** and **Mr. Shirang Bhoot**, NSSS Pvt Ltd., (SSS India Operations) at both the events. Mr. Kumra covered the EU-REACH regulation and the UK-

REACH and Brexit, while Mr. Bhoot spoke about the K-REACH regulation and Poison Centre Notification. At Mumbai, they were joined by Mrs. Akanksha Nagpure, who covered the Turkey REACH and Taiwan Regulation.

Presentation on 'European REACH Regulation – for Non-EU manufacturers'

By Mr. Shisher Kumra, Executive Director, SSS Europe

The technical session began with Mr. Kumra's presentation on EU-REACH and he started by explaining about how the abbreviation 'REACH' is derived.

Registration: Mr. Kumra explained in detail, the registration procedure within REACH regulation and the data requirements within the registration process.

Mr. Kumra elaborated on the following points:

Sections covered within the registration dossier, such as:

- Substance Identification – spectral finger printing
- Uses and Outline Manufacturing
- Phys-Chem endpoint data
- Environmental Fate endpoint data
- Eco-tox endpoint data
- Tox endpoint data
- Chemical Safety Report (> 10 TPA)
- Exposure Scenario (< 10 TPA)
- Substance Classification according to CLP (GHS)

The cost components covered within the REACH regulation along with some ballpoint figures of the letter of access cost and the ECHA registration fees.

Evaluation: Mr. Kumra informed the audience that Registration is only the first step within EU REACH regulation. This would be followed by Evaluation by the European Chemicals Agency (ECHA).



Mr. Shisher Kumra at the Mumbai session

The evaluation may be done in either one or all of the following ways: Substance evaluation, evaluation of testing proposals and compliance checks.

Substance Evaluation: Substance evaluation will be done by the Member State competent authorities (MSCA), wherein the substances will be screened based on their toxic nature, which may pose hazard to human as well as environment. These shortlisted substances will be published in Community Rolling Action Plan (CoRAP) list. The

MSCA will then evaluate the registration dossier submitted to ECHA and send a draft decision to lead registrant and the co-registrants, requesting additional information which will be needed to further check the issues related to the substance. Registrants can defend the additional requirements demanded by the MSCA. Based on the response from registrants, either the decision

will be amended or the final decision for additional data will be issued to registrants with deadline for updating the dossier with this additional information. These evaluations will result in the following:

- A proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitizers or other effects.
- A proposal to identify the substance as a substance of very high concern (SVHC).
- A proposal to restrict the substance.
- Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

Evaluation of Testing Proposals: The second type of evaluation will be the evaluation of testing proposal, where ECHA will check if the test, which is proposed by the lead registrant, is really needed to be conducted or not. Based on the requirement, ECHA will ask the lead to either perform the test or will reject the testing requirements.

Compliance Check Evaluation: Third evaluation is the compliance check evaluation, wherein ECHA will check if all the data, which is presented in the dossier, meets all the REACH requirements and in case of doubt, ECHA may ask for additional testing from the registrants.

ECHA may also check the company size checking, which is commonly known as *SME verification process*. Within this process, ECHA will check all the documentary evidences to support the SME claim put forth by the company and if it is found to be failing the SME definition, then ECHA may charge a penalty to such companies who wrongly claim SME status in order to avail the benefit of reduced ECHA registration fees. Thus companies claiming SME status, are advised to recheck their company sizes and rectify the same in advance, if there is any change, to avoid such penalties.



Participants at Mumbai workshop

Presentation on 'Introduction to Revised K-REACH and Sub-ordinance'

By Mr. Shrirang Bhoot, CTO, NSSS Pvt Ltd., (SSS India Operations)

Mr. Bhoot started by elaborating how the Korean Toxic Chemicals Control Act (TCCA) was implemented by the Ministry of Environment (MOE), Korea for the overall management and control of industrial chemicals and consumer chemical products in Korea. He also explained that Toxic Chemicals Control Act (TCCA) has two major regulations which are executed as follows:

- 1) Registration and evaluation of Chemical Substance act (K-REACH)
- 2) Chemicals Control Act (CCA)

He went on to explain in detail about K-REACH regulation which was enforced in 2015, which involves registration of chemicals, Hazard and risk assessment, Authorization, substance

designation, supply chain management communication, Management of high concern product and the use and tonnage reporting.

He also mentioned about the emergence of regulation, the Korea Existing Chemicals Inventory (KECI) which was issued jointly by the Ministry of Environment and Labour in Korea and includes >46000 existing chemicals substances. The free online inventory is available at <http://ncis.nier.go.kr>. The inventory has different lists of substances namely Priority Existing Chemicals list (PEC), Toxic chemicals, Restricted substance, prohibited chemicals and Accident prevention chemicals. He also introduced SSS Korea portal where the implications for the individual CAS number can also be searched easily at a single click at <https://ssskorea.com/searchpage/>.

Mr. Bhoot further presented the substance criteria that brings along Registration obligation, as given below:

- New chemical substances used > 0.1 ton/year
- Existing chemical substance used >1 ton /year (pre-registration is required). After pre-registration, these pre-registered substances will benefit from a transitional period. The transitional periods are varied depending on the pre-registration tonnage band and hazards of substance.
- Priority existing chemicals (PECs)
The deadline for PEC chemicals has ended, therefore, with termination of grace period, registration is required prior to manufacture or import for anyone who intends to manufacture or import 1 ton or more of PEC substances per annum.
- Polymers are Not exempt from registration.
Although polymers are subject to registration, a considerable number will not need to be due to the 'low concern polymer exemption (LCP).
- Phase-in substances which are also Priority control substances (PCS)
These substances had to be pre-registered under K-REACH between 1 Jan. 2019 and 30 Jun. 2019. The priority control substances are designated and publicly notified by the Ministry of Environment as they are hazardous to humans and the environment, carcinogenic, mutagenic, toxic for reproduction or disruptive to endocrine system to human beings or animals.

Mr. Bhoot, further, shared the timeline for registration along with tonnage bands as follows:

- CMR Substance (1t/a and above) and existing substances (1,000 t/a and above) - 31 Dec. 2021 Deadline.
- Existing Substance (100-1000t/a) - 24 Dec. 2024 Deadline.
- Existing substance (10-100 t/a) - 27 Dec. 2027 Deadline.
- Existing substance (1-10t/a) - 30 Dec. 2030 Deadline.

Further, Mr. Bhoot added information regarding Substance obliged for notification in K-REACH as per the following requirements:

- New substance < 100kg/y (notification is required with less data requirements from 2020.
- Product notification and reporting of product containing hazardous chemical substance (priority control substance)

And, briefly explained about requirements of supply chain communication and penalty as follows:

- Downstream users must provide information, such as use purpose, exposure, use and sales quantity of chemical substances, in order for the manufacturer or importer to register or to apply for changes in registration.
- Anyone who yields chemical substances to the recipients, must pass on information (chemical name, hazardousness etc) used for registration or (pre)notification.

Penalty is very high and on breaching of act, penalty up to 10 million USD or 5 years of imprisonment per violation AND 5% of sales is unavoidable.

He further elaborated on the important role of an Only Representative within the K-REACH compliance activity. He concluded with the strategy to be adapted by the industry towards the K-REACH compliance, choosing the position within the CICO and their respective advantages and disadvantages.

Presentation on 'Introduction to chemical regulations in Turkey (KKDIK) and Taiwan (TCCSCA)' By Mrs. Akanksha Nagpure (At Mumbai only)

Mrs. Akanksha Nagpure, AGM, NSSS Pvt. Ltd. presented on Turkey REACH and Taiwan regulation. The presentation focused on the various aspects of both the regulations, elaborating the similarities and differences they shared with the EU REACH regulation.

The **Turkey REACH (KKDIK)** regulation requires all the substances being manufactured/ placed into Turkey in quantities above 1 ton to be **pre-registered by 31st December 2020** followed by **registration till 31st December 2023**. The registration deadline is not dependent on the tonnage. The registration dossier and the Chemical Safety Assessment and Report can only be prepared by **Certified Chemical Experts**. Post registration also, the SDS can only be prepared by the Certified Chemical Expert. The non-Turkey manufacturers can appoint an **'Only Representative'** (similar to EU REACH) for taking care of the compliance requirements.

The Taiwan regulation (TCCSCA) has been amended recently in 2019. While the pre-registrations for the Taiwan Chemical regulation have already been completed in 2015, the registrations would only be required for the Priority Existing Chemical (PEC) substances. For all other substances, the obligation of annual reporting would be applicable. The regulation sets out different deadlines as per the tonnage of the PEC substances. The provision of late pre-registration is also available in the regulation. It sets a tonnage threshold at 100kgs for the pre-registration and registration of substances. New chemical registrations can be of 3 types: standard; simplified and small quantity. The concept of 'Only Representative' is not present in the Taiwan Chemical regulation.

The presentation also elaborated the industry obligations for compliance within both the regulations and the further steps were advised accordingly.

Implications of Brexit – By Mr. Shisher Kumra

Next followed a presentation on 'Implications of Brexit' by Mr. Shisher Kumra. Mr. Kumra presented a brief background about Brexit and how the process has been initiated where the UK will be separated from European Union. As per current status, the UK is scheduled to be separated on the midnight of 31st January 2020 and will no longer be a part of the EU from 1st February'2020. (*This*

date is, however, yet uncertain and would be based on the forthcoming elections in the UK in December).

Mr. Kumra also briefed about who all will be implicated **in case Brexit happens**. Companies having a supply chain connected with UK will be directly implicated in this situation. Companies which are dependent on the registrations done by their UK buyer will no longer be able to use their registration numbers and will be directly implicated with Brexit. Those who have UK based OR need to transfer their registrations to an OR based in the EU or else their registrations will be cancelled. Also, companies exporting the chemicals via a UK based distributor will be no longer able to use their distributor.

If there is **No-Deal Brexit**, which will be also called as Hard Brexit, then there will be no agreement between UK and EU. The UK will have separate domestic regulation, which will be similar to EU REACH and it will be known as UK REACH. It will be effective from 1st February, 2020 and all companies who intend to export the substances to the UK, need to do the notification in UK REACH IT system. All non-UK based companies can appoint an only representative, who can act on behalf of non-UK companies, to comply with the regulatory requirements. Also, those companies who will do the notifications, will get an extended time of 2 years from date of Brexit, for submitting the complete registration dossier. Also, the letter of access issued in EU REACH registration needs to be re-investigated to check the possibility to include the access of data for UK REACH registration as well. It will have financial obligation on all registrants as they also have to pay the registration fees to UK authorities at the time of final registration of the substance.

Mr. Kumra finally concluded by affirming the implications of UK REACH, but also assured that SSS is available for all possible help to the industry and also assured that SSS will come up with more such events to make the industry aware and alert about the changing regulatory trends.

In conclusion, Mr. Kumra also shared some updates on the *Indian chemical regulation*, which is expected to come into effect shortly. He briefly informed about the current status wherein it is likely to be included within the Environmental Protection Act, which will have a separate rule for the chemical compliance in India. It will be not as complicated as EU REACH but, more likely, will have basic notification of chemicals as a first step. In the second stage, all notifiers of the same chemical have to agree on the classification of that substance and the same will be submitted to the authority. There will be separate Chemical Safety Board, which will be responsible for managing the compliance requirements. They will scrutinize the substances internally and identify the substances which are more hazardous in nature, which may further be subjected to registration. The regulation is currently in the draft stage and is expected to come into effect shortly.

The session concluded with a Q&A session and the following questions were addressed during the event:

Q. How is a polymer treated within K- REACH? How are the different grades of polymer handled, in cases where the CAS number remains same for all grades?

A. All the polymers which qualify as phase-in substances need to be first pre-registered and further registered by the companies based on the tonnage band and respective deadlines. Polymers need to be checked for exemption criteria as well, based on their molecular weight and structural details and may need to apply for exemption from registration, if they meet the exemption criteria. In case

of different grades with same CAS number, the exemption criteria needs to be checked first or it can be subjected to registration based on tonnage band and classification of the substance.

Q. For a phase-in substance, what is the advantage, if it is already registered in EU REACH?

A. There is no direct advantage for the substance which is already registered in EU. But since all dossier is ready as per EU requirements, it can be converted as per Korean requirements easily. But the cost of letter of access needs to be discussed separately with the lead registrants and there could be some discounts available if the LOA is already paid for EU registration since the data used will be the similar.

Q. Does the monomer also need to be pre-registered in K-REACH along with polymers?

A. No, monomers of the polymer need not be pre-registered or registered in case of export of polymers, unlike EU-REACH. Within K-REACH, polymers are subject to pre-registration and registration obligations directly.

Q. How are mixtures treated in K-REACH?

A. Mixtures will be treated in a similar way, as in EU REACH. All components of the mixture exceeding the quantity of 1 ton needs to be pre-registered and further registered based on the tonnage and classification of the individual constituents of the mixture.

Q. Can a merchant exporter register a substance?

A. Yes, merchant exporter, traders can also pre-register and register a substance, through an only representative.

Q. Who is responsible for CLP/SDS related obligations?

A. in case of non-Korean suppliers, the only representative will be responsible for the CLP/SDS related obligations. Also, within Korea, SDS should be compliant to the requirement of IESH regulation.

Q. Are the naturally occurring substances exempted within K-REACH? What document will be needed for exemption confirmation?

A. Yes, the naturally occurring substances are exempted within K-REACH regulation and suppliers need to prepare the exemption document as a proof for the authorities in case verification is done. They can prepare the statement of exemption with all analytical proof on their letterhead for the authorities.

Q How is pre-registration handled within Turkey REACH?

A. SSS has a Turkey based legal entity which will act as the only representative, Thus, any non-Turkey manufacturer can appoint SSS to do the pre-registration and further registration process.

Q Is there a possibility of only representative within Taiwan regulation as well?

A. As of now the only representative option is not available within Taiwan regulation, but it will be handled by a Taiwanese third party, who can act on behalf of manufacturer to help with Taiwan regulation compliance.

For any further queries, please write to us at: advisor@reach-onlyrep.eu or sk@reach-onlyrep.eu

Thank you!