

Background Note On the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

The Centre for WTO Studies is carrying out a study on the “**European Commission’s Regulation on REACH: Implications for the Indian Industry**”

The study will be submitted to the DoC and the objectives of the study are as follows:

1. To understand the implications of REACH, the nature of its implementation and to identify the barriers it may create for the Indian Industry.
2. To conduct a comprehensive study of its compatibility with WTO provisions, including the TBT Agreement.
3. To identify the grounds, if any, on which the possible violations may be raised in the WTO.
4. To assess whether there is merit in pursuing a WTO dispute and possible counter viewpoints from the EU.
5. To highlight the nature of additional facts and figures required from the government and the Industry, to support any potential claim, in this regard.

REACH is a European Union Regulation of 18 December 2006. (Full title: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (ECHA). It entered into force on 1 June 2007. REACH addresses the production and use of chemical substances, and their potential impacts on both human health and the environment. The objective of this regulation is protection of human health and environment from the hazards of chemicals.

- **Background:** The REACH Regulation is based on the principle that the industry should manufacture, import and use chemical substances with responsibility and care to ensure that under foreseeable conditions, human health and the environment are not adversely affected. This is done by generating all the relevant possible information on the chemicals which would help identify their hazardous properties and come up with measures to manage the same. Another important objective of the regulation is to ensure that in cases where chemical substances of high concern¹ are used, they should eventually be replaced by less dangerous substances.

○ **REACH AND Indian Industry:** REACH presents key challenges for several industry sectors which use chemicals, primarily in the form of:

- a) substantial expense for compliance;
- b) complicated administrative requirements that need to be fulfilled;
- c) potential discriminatory effects on non-EU manufacturers and merchant exporters of chemicals; and its practical impact of incentivising reliance by EU manufacturers of articles and preparations, on EU based producers and suppliers of chemical substances, to the prejudice of foreign producers and exporters into the EU.

This may have serious consequences for the existing and potential expansion of the market for chemical exports into the EU and in particular may impact the Small and Medium Enterprises (SMEs).

Implications for the Indian Industry:

- Generation of data for any chemical used in the product being exported to the EU.

¹ Chemicals of high concern are carcinogens, mutagens, reproductive toxicants and those that are persistent or bio-accumulative including endocrine disruptors and persistent organic pollutants.

- The regulation places the Indian exporters at a disadvantageous position as the regulation requires the Indian exporters to register their products through an **Only Representative** present within Europe i.e. a natural or legal person established within the community.
 - Costs are incurred relating to
 - Preparation and maintenance of technical dossier;
 - Cost of engaging the Only Representative;
 - Cost of testing.
 - The additional cost burden to the Indian Industry in terms of:
 - Disclosure of confidential materials regarding production, processing including those which are protected under IPR.
 - India needs adequate infrastructure for the testing requirements of REACH for the exporters as currently there are very few labs in the country which would be able to provide certificate for REACH compliance.
- ❖ **Registration Under REACH:** Substances manufactured or imported in quantities exceeding 1 ton per year must be registered with the ECHA in Finland. There is no manufacture or import without registration. Manufacturing or importing without registration is considered as an economical offence in the Netherlands and may be punished with imprisonment, community service or a considerable fine
- **Application Of REACH :** REACH applies to:
 - ❖ **Substances:** chemical elements & their compounds
 - ❖ Preparations : mixtures or solutions of two or more substances
 - ❖ Articles with substances that are intended to be released under normal or reasonably foreseeable conditions of use (for example, printer ink cartridges)

▪ **Fees and Charges as under the REACH Regulation**

An annual fee is to be paid according to Article 74 of the REACH and in accordance with EU Regulation: 340/2008. The fee shall be paid in accordance with the tonnage range of the substance and a reduced fee is set for SME's. The fees and charges are to be paid in Euros by all manufacturers or importers of chemical substances in the EU. However no fee for registration is levied on the substances in quantity between 1-10 tonnes where the Technical Dossier contains the full information as required under Article 10, Annex VII.

There are several types of fees and charged as prescribed under the REACH and these can be summed up as follows:

1.1.1 Registration: Computed as according Annex 1 of EC Regulation 340/2008.

Tonnage Range	Enterprise		Medium**		Small		Micro	
	Single	Joint	Single	Joint	Single	Joint	Single	Joint
1-10*	1600	1200	1120	840	640	480	160	120
10-100	4300	3225	3010	2258	1720	1290	430	323
100-1000	11500	8625	8050	6038	4600	3450	1150	863
Above 1000	31000	23250	21700	16275	12400	9300	3100	2325

* As per Article 3.1 of the EU Regulation 340/2008, no fee shall be levied for the registration of a substance, in the quantity of 1-10 tonnes where the registration contains all information as required under Annex VII, EC regulation 1907/2006.

****Definition of Small, Medium and Micro Enterprises:** On May 6th 2003, the Commission adopted a new Recommendation 2003/361/EC regarding the SME definition, which replaced Recommendation 96/280/EC as from 1 January 2005. The classification is given below:

Enterprise Category	Head Count	Turnover	Balance Sheet
Medium-size	<250	≤50 million	≤43 million
Small	<50	≤10 million	≤10 million

Minor	<10	≤2 million	≤2 million
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The revision takes account of the economic developments since 1996. Although different criteria are recognized world over for distinguishing, small and medium enterprises, for the purpose of REACH, only Recommendation 2003/361/EC shall be taken into account.²

- 1.1.2 **Confidentiality:** Under Article 10 (a) (xi) of the REACH Regulation, the importer can request for certain information to be kept confidential and not displayed on the internet as it may harm their commercial interests. The application must be made in accordance with Article 77(2)(e) along with a fee provided in Annex IV of the EC Regulation 340/2008. The Annex has provisions for a reduced fee for SME's. Certain items for which confidentiality is requested are; information in the safety data sheet; trade name of the substance; degree of purity or the identity of the impurities or additives etc.
- 1.1.3 **Authorization:** Annex VI lays down the fee structure for authorization of certain chemicals if they fall under PvB, vPvB, CMR category as according to Article 62 of the Regulation. Along with a base fee an additional fee is charged per substance and use of the substance. A reduced fee is levied on SME's.
- 1.1.4 **Amendment:** Annex III lays down the fees for making any sort of amendments or updates to the registered product. Fees is charged for making amendments to the initial tonnage band applied for, changes in the legal identity of the applicant etc.
- 1.1.5 **Appeal:** A fee is levied for any submission of an appeal as against a decision of the Agency under Article 92³ of EC Regulation 1907/2006; as laid down under Annex VIII of EC Regulation 340/2008.

Purpose Of These Industry Consultations : The purpose is in order to include the Indian industry and get its feedback on how the industry is meeting the challenges of complying with the REACH regulation, what its feedback is regard to the costs of compliance factor, whether such costs translate into substantial business costs for the companies , whether such costs are deterring the units from doing business with the EU and the possibility of challenging the REACH regulation at the WTO dispute forum.

² Article 2 of Commission Regulation (EC) No. 340/2008

³ Appeal can be against a decision of the agency pertaining to restriction, authorization or a product exempted from registration, as it falls within category of process or product for research and development.