

Status of India-REACH Implementation

Gagan Kumar*

I. Overview

The chemicals industry in India is highly diversified, covering more than 80,000 commercial products. It can be broadly classified into bulk chemicals, specialty chemicals, agrochemicals, Petrochemicals and Polymers and Fertilizers. India is also a global dye supplier, accounting for approximately 16% of the world production of dyestuff and dye intermediates. The current market size of the chemicals and petrochemicals sector in India is worth \$178 billion and is expected to double in size to \$300 billion by 2025. Demand for chemical products is expected to grow at approximately 9% per year during 2020-25. The Indian chemical industry employs more than 2 million people. India ranks 6th largest in the World and 4th largest in Asia for chemicals sales, is the third-largest consumer of polymers in the world and is fourth-largest producer of agrochemicals in the world.

India is a signatory to international conventions and treaties¹ and has created local regulations to enforce them and has also develop knowledge in the area of safety.

To improve the quality of chemicals, petrochemicals and trade intelligence, the Department of Chemicals and Petrochemicals in India has brought around

55 chemicals under mandatory BIS (Bureau of Indian Standards) license requirements pursuant to the BIS Act of 2016². The BIS (Conformity Assessment) Regulations of 2018³ introduced various quality control orders (QCOs). The government will add more chemicals and the list is expected to grow to some 100s in the near future. Once on the list you are required to obtain a BIS license and introduce ISI mark labels on your product before importing them into India within 180 days. Foreign manufacturers of such chemicals are required to appoint an authorized India Representation to submit their applications for an India BIS license and its maintenance upon expiry.

Recently, authorities proposed an Action Plan on the Implementation of a Circular Economy in Toxics and Hazardous Industrial Wastes covering chemicals and environment chapters to contribute to the action plan.

The Ministry of Labour and Employment Government of India has recently introduced The Occupational Safety, Health and Working Conditions Code, 2020⁴. The Code consolidates 13 existing Acts regulating health, safety, and working conditions. These include the Factories Act 1948⁵, the Mines Act 1952⁶ and the Contract Labour (Regulation and Abolition) Act 1970⁷. The code will apply to establishments employing at least 10 workers. However, certain provisions of the Code, such as health and working conditions, apply to all employees. One of the duties of the employer is to provide a workplace that is free from hazards and additional duties include the provision of a risk-free work environment and instructing employees on safety protocols.

Currently, India's chemicals industry is delicensed, except for few hazardous chemicals which are governed by the existing regulatory environment.

During the twelfth 5-year plan (2012-2017), several initiatives were proposed to boost the growth of the Indian chemical industry including a plan to expedite the consolidation of multiple legislations governing the chemical industry into one Integrated Chemical Legislation by the government. This regulation shall act like EU REACH, the objective of India's REACH-like law is to ensure a high level of protection for human health and the environment as

* Gagan Kumar is Managing Director of REACHLaw India Private Limited; Email: <gagan.kumar@reachlaw.fi>

1 The Chemical Weapons Convention (CWC), Rotterdam convention on PIC (priority informed consent procedures), Stockholm Convention on POPs (persistent organic pollutants), SCOMET (special chemicals, organisms, materials, equipment and technologies) for dual-use concept.

2 See, <<https://www.bis.gov.in/wp-content/uploads/2020/12/BIS-Act-2016.pdf>> accessed 24 October 2022.

3 See, <https://www.bis.gov.in/wp-content/uploads/2019/03/BIS_CA_12032019.pdf> accessed 24 October 2022.

4 See, <https://labour.gov.in/sites/default/files/OSH_Gazette.pdf> accessed 24 October 2022.

5 See, <https://labour.gov.in/sites/default/files/Factories_Act_1948.pdf?msclkid=4bc36633cf7a11eca45dca5b9283edc> accessed 24 October 2022.

6 See, <<https://www.indiacode.nic.in/bitstream/123456789/2168/3/A1952-35.pdf?msclkid=664d4e51cf7a11ecb6480d29a4bd4ecb>> accessed 24 October 2022.

7 See, <<https://labour.gov.in/sites/default/files/TheContract-Labour1970.pdf?msclkid=96356ef8cf7a11ec93f1a3f5adc4803e>> accessed 24 October 2022.

well as providing safety procedures for the manufacture, handling and import of hazardous chemicals - and preparedness and management of chemical accidents related to hazardous chemicals.

II. Background

India circulated the fifth draft of its REACH-like chemicals law termed the 'Chemical (Management and Safety) (CMS) Rules 20XX (a.k.a. India REACH) in August 2020.'

Once entered into force it then shall supersede the Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules 1989⁸ and Chemical Accidents, Emergency Planning, Preparedness and Response (CAEPPR) Rules 1996,⁹ and will regulate chemicals currently in use and those transported into, or manufactured in, India.

The new law will cover notification, registration, restriction, and prohibition of chemicals as well as UN GHS v.8 Safety Data Sheet (SDS), labelling and packaging requirements related to the use of substances, including those in mixtures and articles, and intermediates placed, or intended to be placed, on the market in the country in quantities above one tonne/year.

The exemption applies to the following:

- radioactive substances;
- substances under customs supervision, not being placed on the market in India;
- substances stored in customs-free zones with the aim of re-exporting;
- wastes, as defined in the Hazardous Waste Management Rules 2016;
- substances used for the purposes of defence;
- substances used as food for human beings or animals, including nutrition; and
- substances set out in Schedule IV (includes 15 entries covering both substances listed with CAS number as well as exemptions based on criteria).

III. About India REACH

1. What is India REACH?

India-REACH is India's chemical regulation currently in draft stage known as "Draft Chemicals (Management and Safety) Rules" or CMS Rules a.k.a. India REACH.

It will control the safe use of chemicals in India along the lines of EU REACH principles of no data, no market and achieve similar objectives including safety and accident preparedness from existing regulation on hazardous chemicals.

2. Who Needs To comply?

Under these rules, Indian manufacturers, Indian importers along with Authorised Representatives (ARs) appointed by foreign entities covering both manufacturers and traders are required to comply. In addition to these requirements, local companies must also comply with hazardous chemicals management requirements.

3. What Are The Main Requirements and How Much Do They Cost?

The main requirements under India REACH pertain to notification of annual reporting, registration, safety data Sheets/labelling and hazardous chemical compliance.¹⁰

- a. Notification (remains the main requirement under India REACH)

All Indian manufacturers or Indian importers or authorised representatives of foreign entities shall submit a notification to the authority of all existing substances placed in quantities greater than 1 tonne per annum.

After the expiry of the Initial Notification Period, all New Substances must be Notified at least 60 days prior to the date on which they are Placed in Indian Territory in quantities more than 1 tonne per annum.

Notification dossier demands information on details of Notifier, identity of the Substance (this also

8 See, <<https://moef.gov.in/en/manufacture-storage-and-import-of-hazardous-chemical-rules-1989?msclkid=e3ef8fc8cf7a11ec92b7abb7f97f292e>> accessed 24 October 2022.

9 See, <<https://dste.py.gov.in/ppcc/pdf/act/THE%20CHEMICAL%20ACCIDENTS%20RULES-1996.pdf?msclkid=ff96ed4fcf7a11ec92b5c03eb7742044>> accessed 24 October 2022.

10 See Figure 1 for draft regulation structure and figure 2 for Scope, Requirements and Timelines.

includes reporting of spectral data), Uses, hazard classification, details of top 3 Downstream users (DU) and actual annual quantities in MT.

All notified substances shall undergo Annual Reporting requirements no later than 60 days after the end of each calendar year. Additionally, any changes or additions to the information submitted at the time of Notification must be updated. You also need to update your SDS according to UN GHS v8 to be included in the notification dossier.

An Authority fee between 300 to 7000 EUROS per substance per legal entity is applicable for notification submission. It varies with tonnage band. In addition, you need to consider spectral data charges, SDS update charges and consultant fees.

Notification is like a co-registration dossier in EU REACH, if you exclude the data sharing process but include C&L, DU information and SDS along with yearly reporting requirements.

b. Registration

It is important to note that not all notified substances require registration. All Manufacturers, Importers and Authorised Representatives that have Placed or are intending to Place in Indian Territory a Substance listed as Priority Substance in Schedule II in quantities greater than 1 tonne per annum must register such substance within one and half years from the date of inclusion of the substance in Schedule II. Currently, there are 750 chemicals on the Schedule II list which is expected to grow following the evaluation of notified substances.

Registration below 1tpa may also be required and list of such substances may also be published in Schedule II.

Substances used above 10 tonnes per annum shall perform a Chemical Safety Assessment and submit a Chemical Safety Report.

A priority substance means:

- any Substance falls under any of the following Hazard Classifications of UN GHS Rev. 8
 - Carcinogenicity and/or Germ Cell Mutagenicity and/or Reproductive Toxicity (CMR) and categorised as Category 1 or 2, or
 - Specific Target Organ Toxicity (Repeated Exposure or Single Exposure) Category 1 or 2;
- or
- any Substance which fulfils the criteria of Persistent, Bio-accumulative and Toxic (PBT) or

very Persistent or very Bio-accumulative (vPvB); or

- any Substance listed in Schedule II (*Note: these substances only qualify for registration*);

An Authority fee between 400 to 10 000 EUROS per substance per legal entity is applicable for registration submission. It varies with tonnage band, joint or individual submission. In addition to authority charges, you need to consider testing or data access fees and consultant fees.

c. Hazardous Chemical Compliance

The draft regulation also covers the import of priority substances or hazardous chemicals into India. For companies handling hazardous chemicals in India at their factories and supplies, the following requirements apply:

- Transport of hazardous chemicals.
- Submission of Information relating to Industrial Activity.
- Site safety report (simplified/standard), revision, and its updates.
- Safety audit report, revision, and its updates.
- Import of Priority Substances or Hazardous Chemicals.
- Preparation of on-site emergency plan.
- Support in the preparation of off-site emergency plan.
- Notification of chemical accidents.
- Information to be given to persons liable to be affected by a Major Chemical Accident.
- Safety Data Sheet: All Notifiers of a Substance or an Intermediate listed in Schedule II or a Hazardous Chemical & manufacturer of articles where a Substance or an Intermediate listed is in.
- Schedule II is present in such Article above a concentration of 1.0 % weight by weight (w/w) are required to maintain and submit an up-to-date Safety Data Sheet in accordance with UN GHS v8 and share such Safety Data Sheet with the Downstream User of the Substance.

4. Structure and Duties of Authorities Involved

To implement India REACH, a **National Chemical Authority – NCA** – has been set up which consists

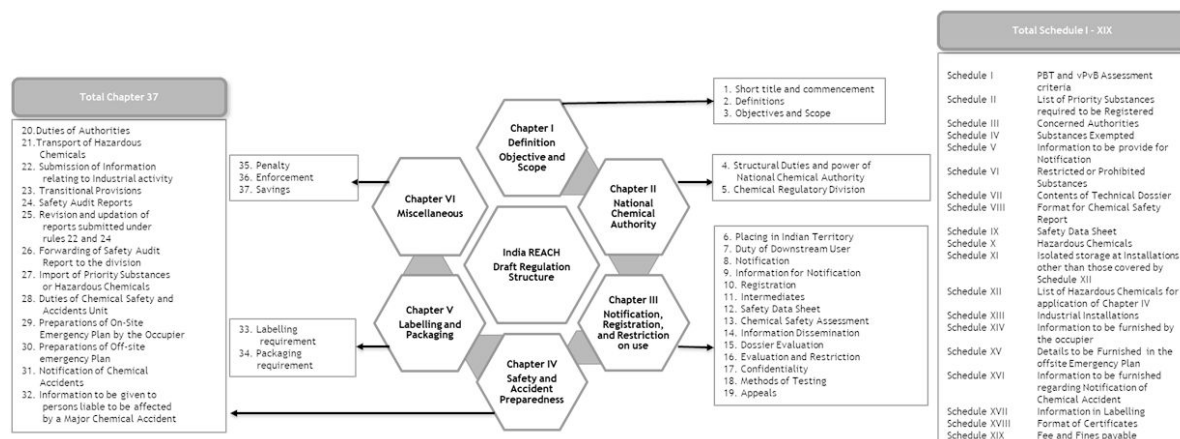


Figure 1: Draft regulation structure

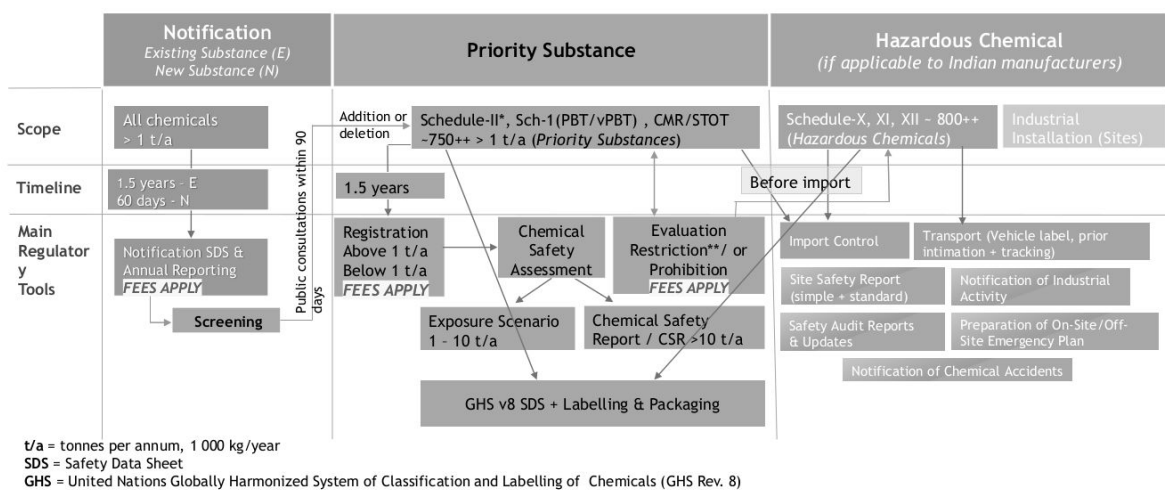


Figure 2: Scope, Requirements and Timelines

of the Steering Committee, the Scientific Committee, Risk Assessment Committee, and the Chemical Regulatory Division (CRD also known as ‘division’). Figure 3 explains the structure of authorities w.r.t. requirements.

Wherein, the Steering Committee shall oversee technical and administrative matters, prepare, and publish an annual report regarding the activities of the Division, and approve an annual budget for the functioning of the division. The committee shall meet at least once every 90 days.

Both the **Scientific and Risk Assessment Committee** will access quality of information submitted by applicants.

The **Chemical Regulatory Division** called as CRD or ‘division’ is Petroleum and Explosives Safety Organisation (PESO) shall discharge the duties of the secretariat of the NCA and shall carry out all functions as required under these draft Rules. PESO is already in existence since 1898 and currently implements various regulations as listed under figure 4. The division consists of total 8 units as;

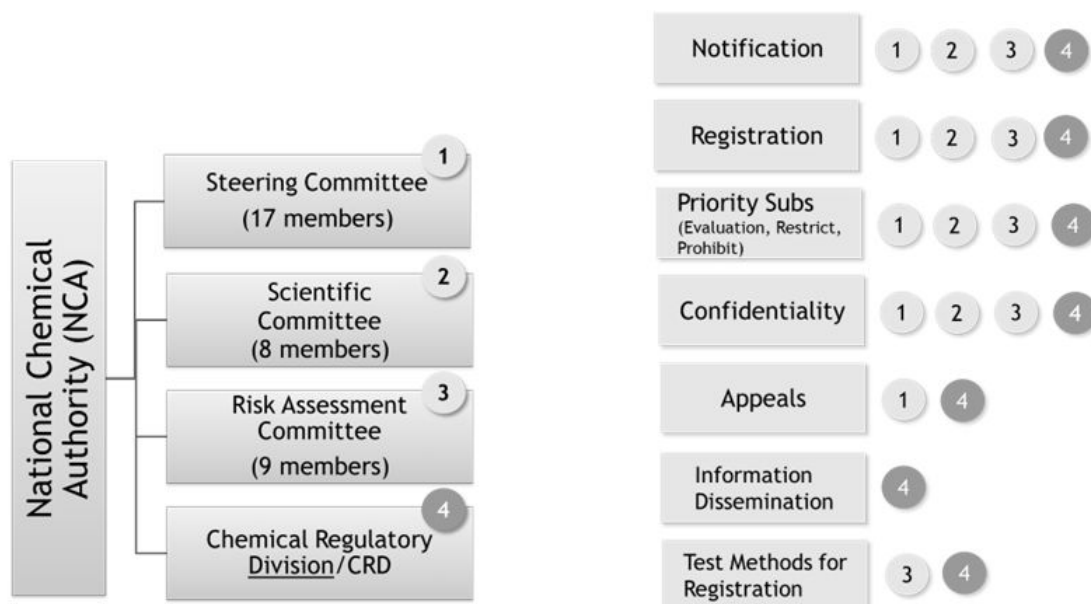


Figure 3: Explains the Structure of Authorities w.r.t. Requirements

- Chemistry Unit
- Toxicology Unit
- Chemical Safety & Accidents Unit
- Packaging & Labelling Unit
- Techno-legal Unit
- Priority Substance Unit
- Information Technology Unit
- Socio-economic Unit

For hazardous chemicals, various existing authorities are involved in the implementation and enforcement (see table 1).

5. Use of Data Submitted in REACH or REACH Like Regulations in Other Countries

You are required to generate data on your substances for notification & registration purposes under India REACH and use them for evaluation purposes later upon submission of the dossiers.

For registration, the registrants shall comply with the testing methodology laid down in the Organization for Economic Co-operation and Development (OECD) guidelines for the testing of Chemicals. The

tests must be carried out in NABL (National Accreditation Board for Testing and Calibration Laboratories)¹¹ accredited or GLP-certified laboratories.

To avoid repeated testing, the existing test data must be considered prior to requiring new testing. All efforts should be made to derive the required data using alternative methods recommended by OECD.

It is allowed to use previously submitted data if it meets the quality to fulfill the data requirement of your dossiers.

IV. Conclusion

The above information is correct as of the 24th August 2020. The sector continues to seek clarity and has proposed to include additional information mainly to cover requirements of polymers and data for each tonnage band for the registration of priority substances, fees, etc.

If you are one of the actors who needs to comply with India REACH requirement then the first step is to work on your substance inventory for each legal entity, check the information available in-house w.r.t data requirements, understand if you require any testing or access to data, review your existing safety data sheets if this requires revision according to UN GHS v.8.

11 See, <<https://nabl-india.org/>> accessed 24 October 2022.

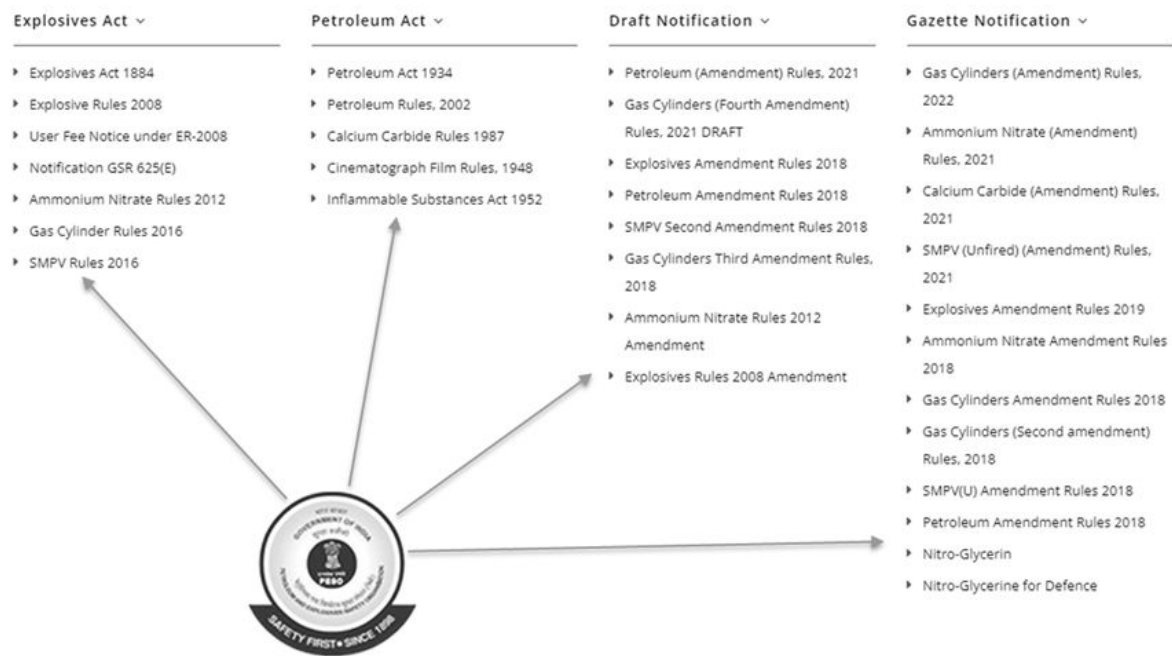


Figure 4: Various regulations under PESO

Table 1: Hazardous chemicals authorities

Authorities	Duties
Chief Inspector of dock safety appointed under the Dock Workers (Safety, Health and Welfare) Act, 1986 –fnref:12–within the dock area. Chief inspector of mines appointed under the Mines Act, 1952 within the mine area. Atomic Energy Regulatory Board appointed under the Atomic Energy Act, 1962–fnref:13–. Chief safety officer appointed with concurrence of the Division for any Industrial Pocket notified under any central or state legislation. Chairman Central Board of Indirect Taxes & Customs (CBIC) for Customs Warehouses. Chief inspector of factories appointed under the Factories Act, 1948 for areas for not covered under I to V.	Approval and notification of industrial activities and site safety report Safety audit report Issuance of improvement notice Notification of chemical accidents Acceptance of on-site emergency plans Preparation of off-site emergency plans Analysis of a major accident
Chief inspector of dock safety appointed under the Dock Workers (Safety, Health and Welfare) Act, 1986	Import of priority substances or hazardous chemicals
Chief controller of explosives appointment under the Explosive Act, 1884–fnref:14–.	Remaining industrial installations and isolated storages dealing, all pipelines including inter-state pipelines dealing with hazardous chemicals
State pollution control boards	Transport of hazardous chemicals

If you are a downstream user in India, you are required to purchase only India REACH compliant ma-

terials from your suppliers as most of the requirements fall within 18 months of regulation coming in-

Table 2: Compares India's REACH-like regulation with EU REACH, Turkey KKDIK, and Korea's REACH

Requirement	EU REACH	Draft India REACH	Turkey KKDIK	Korea REACH
Pre-registration	Yes, but no longer possible	Does not exist	Yes, late pre-registration is possible	Yes, late pre-registration is possible
Notification & annual reporting	No	Yes	No	No
Registration	New and existing over 1 tpa	Only for chemicals listed in Schedule II (750) above and below 1tpa, more chemicals to be included in Schedule II after notification.	New and existing over 1 tpa	New and existing over 1 tpa
Polymer Registration	Exempted but not monomers (REACH revision requires polymer registration)	Not defined	Exempted but not monomers	Yes, only polymers meeting the criteria of polymer of low concern (PLC) are exempted from registration
Data requirement	More volume, more data	Same principle, data vs volume – not yet defined	More volume, more data	More volume, more data
Hazardous chemical compliance	No	Yes	No	No
Only representative concept	Yes	Yes, with criteria	Yes	Yes
SDS	Yes	Yes	Yes, to be certified and may be submitted to the authority	Yes, to be submitted to the authority

to force. The Indian REACH regulation currently in the draft stage is expected to be delayed whereas the

extent of the delay is not known by the time this article is out for publication.