

Introduction of Chemical Regulations in India

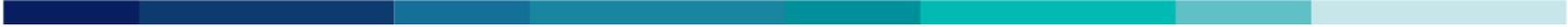
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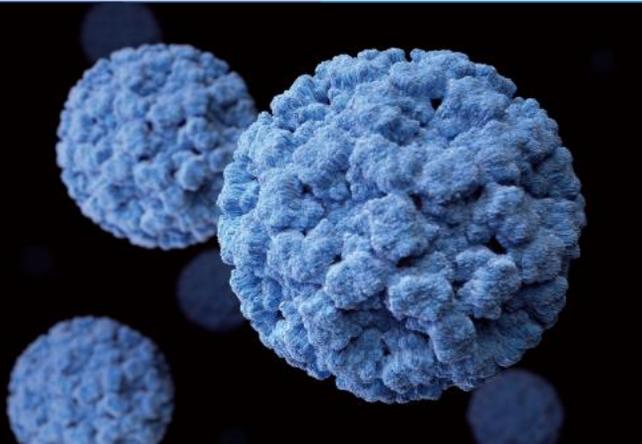
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in India

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Draft of ICMSR – Schedule,
Scope, Organizations

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Chemical Management in India



01

Chemicals Management in India

The legal basis or chemical management rules in India can be found in the Environment (Protection) Act, 1986

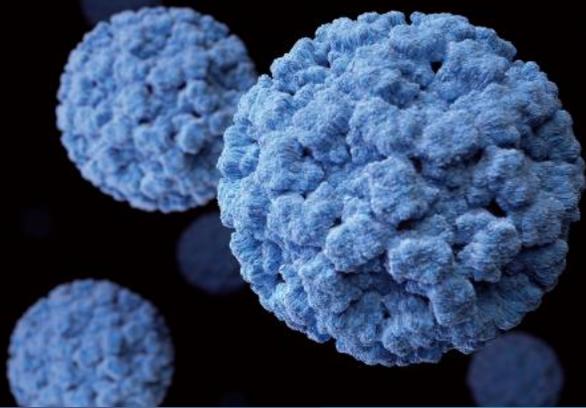
The objectives of this Act are:

- To protect and improve the quality of the environment
- To prevent, control, and abate environmental pollution

Currently, two main sets of rules apply to chemicals management in India

Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989	Chemicals Accidents (Emergency Planning, Preparedness and Response) Rules, 1996
<ul style="list-style-type: none"> • Safety reporting • Emergency planning • Import of Hazardous Chemicals 	<ul style="list-style-type: none"> • Crisis Groups to deal with chemical accidents • Crisis Alert System

Introduction to the 5th Draft of ICMSR – Schedule, Scope, Organizations



02

Indian Chemicals Management and Safety Rules(ICMSR)

August 24, 2020

The ICMSR will replace both sets of rules.

They establish:

- Notification, Registration and Restriction of Substances
- Labelling and Packaging requirements for Substances
- Safety procedures for the manufacturing, handling and import of chemicals
- Preparation for and management of chemical accidents

Chapter I – Definition, Objectives and Scope

Chapter I – Indian National Chemical Authority

Chapter III – Notification, Registration and Restrictions on Use

Chapter IV – Safety and Accident Preparedness

Chapter V – Labelling and Packaging

Chapter VI –

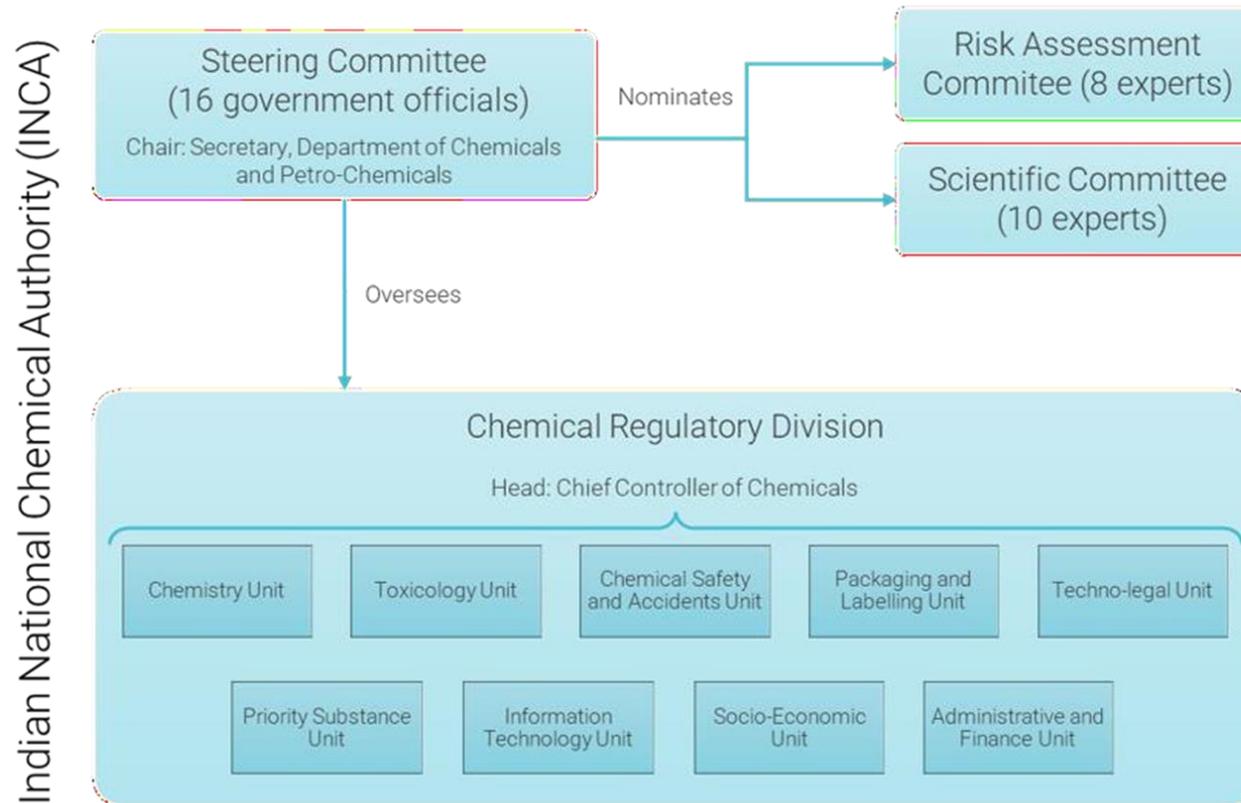
Miscellaneous

Schedules (I to XIX)

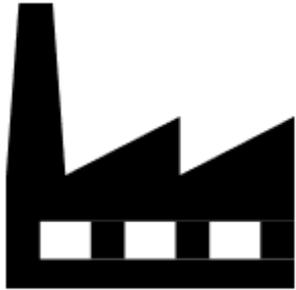
Indian Chemicals Management and Safety Rules(ICMSR)

I	PBT and vPvB Assessment Criteria	XI	Isolated Storage at Installations Other Than Those Covered by Schedule XIII
II	List of Priority Substances required to be Registered	XII	List of Hazardous Chemicals for Application of Chapter IV
III	Concerned Authorities	XIII	Industrial Installations
IV	Substances Exempt for the purposes of Chapter III and V	XIV	Information to be furnished by the occupier
V	Information to be provided for Notification	XV	Details to be furnished in the off-site emergency plan
VI	Restricted or Prohibited Substances	XVI	Information to be furnished regarding notification of a chemical accident
VII	Contents of Technical Dossier	XVII	Information in labelling
VIII	Format for Chemical Safety Report	XVIII	Format of certificates
IX	Safety Data Sheet	XIX	Fees and fines payable
X	Hazardous Chemicals		

Indian Chemicals Management and Safety Rules(ICMSR)



Different Roles



**Indian
Manufacturers**

- Notification and Registration
- Safety and Emergency Planning
- Labelling and Packaging



**Indian
Importers**

- Notification and Registration
- Safe Import of Hazardous Chemicals
- Labelling and Packaging



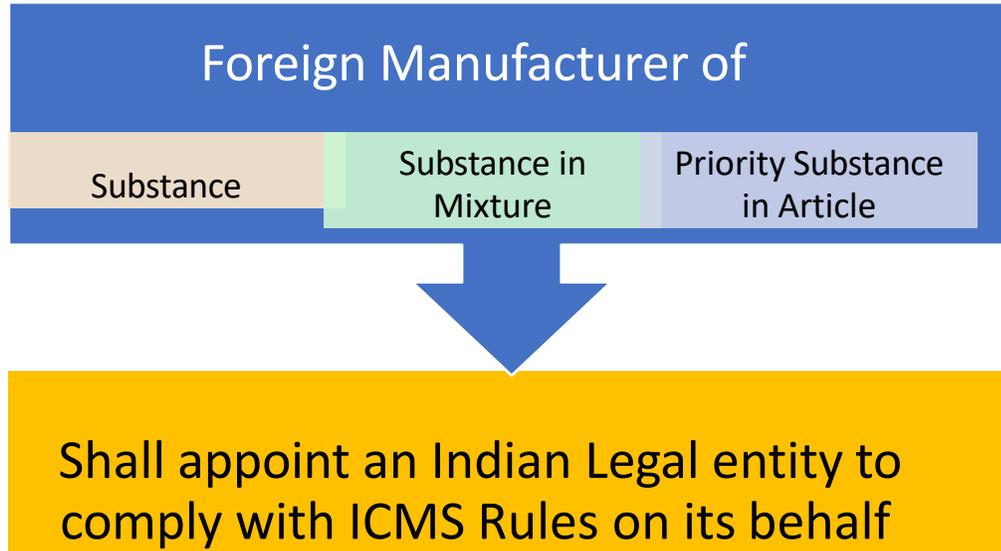
**Authorized Representative
(non-Indian manufacturer)**



**Downstream
Users (DU)**

- Use substances in their industrial or professional activities
- Excludes manufacturers, importers, and end-use consumers
- Must avoid procuring non-compliant Substances

Authorized Representative



- Indian national or entity registered in India
- Can be appointed by foreign entities who want to place Substances on the Indian market
- Responsible for the compliance of the foreign entity appointing them
- Authorized Representative has a similar function as “**Only Representative**” in EU- REACH & K-REACH.

Key Compliance Obligations



Key Compliance Obligations

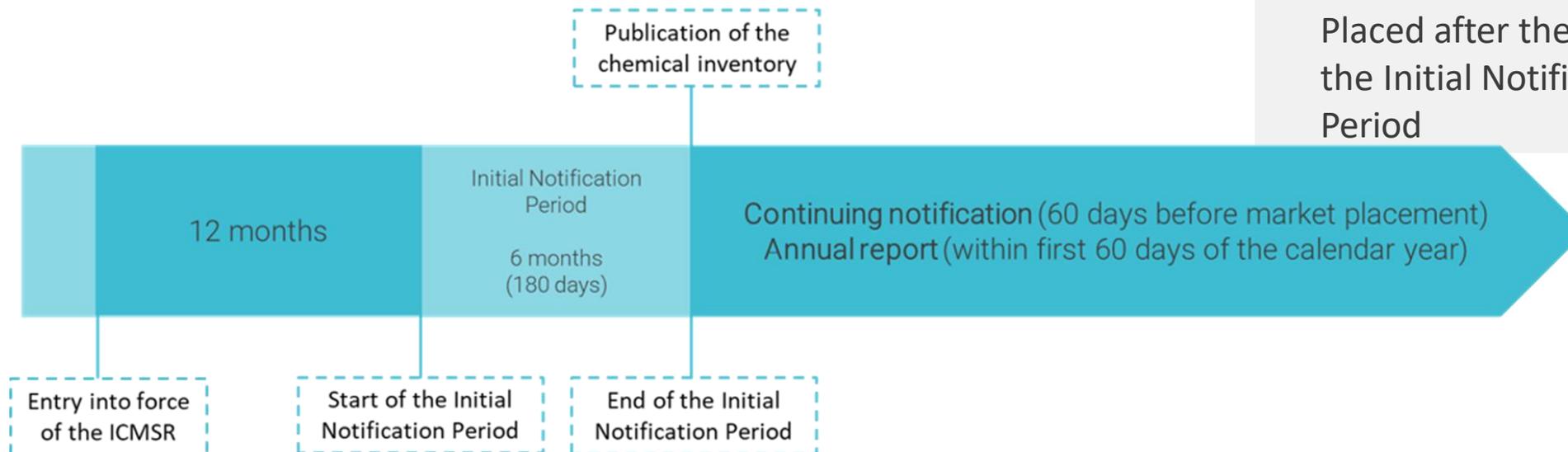
	Scope	Timeline	Updating	Subjects
Notification	All substances	Initial Notification Period: Existing Substances New Substances: Prior to market placement	Annual Report	Manufacturers Importers Authorised Representatives
Registration	Substances listed in Schedule II ("Priority Substances required to be registered)	18 months after inclusion in Schedule II	Annual report Schedule II will be regularly updating	Manufacturers Importers Authorised Representatives

Notification Timeline

- Any operator complying with other regulations – may also notify
- Polymers are not defined within current draft.
- Require to be notified within **Initial Notification Period** – 180 days
- Any operator – that has not notified in Initial Notification Period

All Substances placed in Indian Territory in quantities above 1 tonne per annum (TPA):

- **Existing Substances:**
Placed before the end of the Initial Notification Period
- **New Substances:**
Placed after the end of the Initial Notification Period



Data Requirement for Notification

- Notifier Details
- Substance Identifiers
- Impurities
- Tonnage
- **Substance Structural details & Spectra**
- **Hazard Classification**
- **Uses**
- **Downstream users**
- **Max storage capacity**
- **SDS**

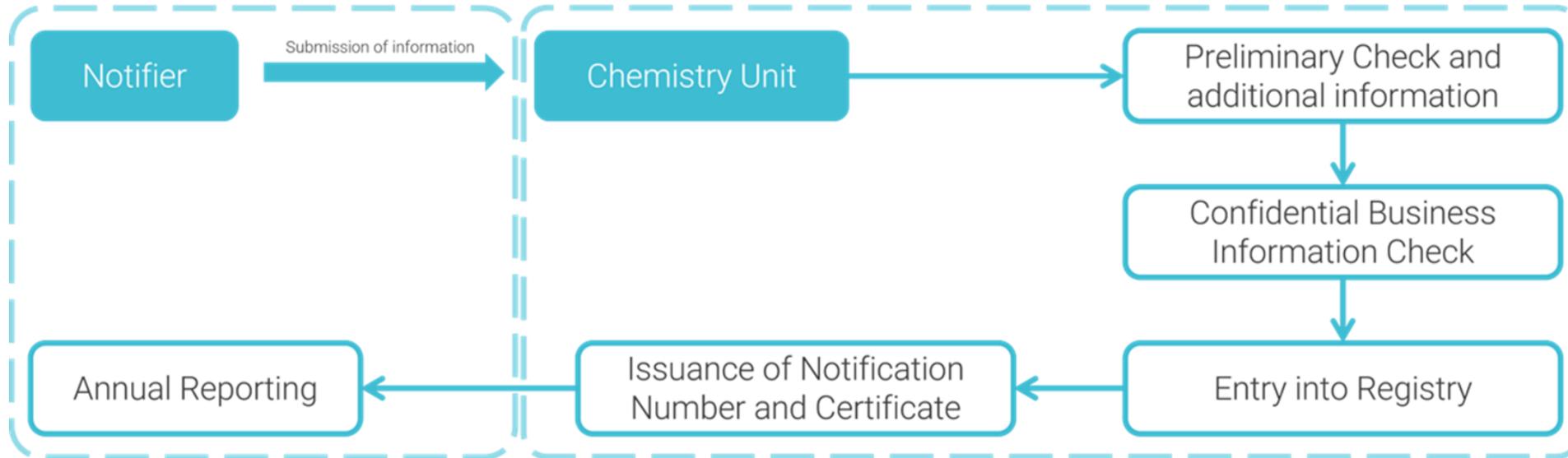
Schedule V - Information to be provided for Notification

1. Details of Notifier:
 - a. Name, address, phone, email of the Notifier
 - b. Name, address, phone, email of the person authorised to submit Notification
 - c. Details of foreign manufacturer, if the Notifier is an Importer or Authorised Representative
 - d. Location of the production and own use site(s), as appropriate
2. List main constituents of the substance with 10% (w/w) or more concentration

S.No.	IUPAC Name	Common Name	CAS No.	Molecular structure	Isomer	% age Conc.
3. List all impurities with more than 1.0% but less than 10% (w/w) concentration
4. For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), give the following details:
 - a. Structural representation of the constituents
 - b. Reaction scheme (including the identity of the reactants and the reaction type)
 - c. Process output (including identity of the precursors, the technology (method of preparation; process terms) and the typical composition)
5. Chemical Structural Details
 - a. Molecular wt.
 - b. Simplified Molecular Input Line Entry System (SMILES)
 - c. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - d. Spectral data:
 - i) High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
 - ii) Infra Red spectra
 - iii) Ultra Violet-Vis Spectrophotometer – spectra
 - iv) Nuclear Magnetic Resonance
6. Hazard Classification of the Substance (*according to eighth revision of UN-GHS*)
7. Chemical uses
8. Name of known Downstream Users (*at least top 3; will be kept confidential*)
9. Actual quantity per annum in TPA (*will be kept confidential under all circumstances*)
10. Maximum Storage Capacity/Maximum quantity stored

(The information contained in the Notification must be based on test reports from NABL accredited labs or GLP labs or any other Published authentic study report.)

Notification Procedure



The ICMSR provides for the public availability of:

- Substance information
- Substance uses
- Substance classification

Confidentiality requests can be made on the basis of:

- Trade secrets
- Proprietary business information
- Other data and information related to intellectual property

Confidentiality may not be requested for:

- Substance classifications
- Endpoint summaries

Notification Fee and Certificate

Substance tonnage band	MSME	Large
1 – 10 TPA	10,000 ₹ (~130 \$)	25,000 ₹ (~328 \$)
10 – 100 TPA	30,000 ₹ (~390 \$)	75,000 ₹ (~984\$)
100 – 1000 TPA	80,000 ₹ (~1,050 \$)	200,000 ₹ (~2,624 \$)
> 1000 TPA	250,000 ₹ (~3,280 \$)	600,000 ₹ (~7,872 \$)

An Enterprise needs to be below both ceilings to fit in a category

Type of enterprise	Investment in Plant and Machinery or Equipment	Turnover
Micro	10,000,000 ₹ (~131,209 \$)	50,000,000 ₹ (~656,046 \$)
Small	100,000,000 ₹ (~1,312,093 \$)	500,000,000 ₹ (~6,560,465 \$)
Medium	500,000,000 ₹ (~6,560,465 \$)	2,500,000,000 ₹ (~32,802,325 \$)

Intermediates

All Transported Isolated Intermediates (TII) needs to be Notified

Intermediates that are Priority Substances (Sch. II) to Be Registered:

- < 1000 TPA – basic registration
- > 1000 TPA – full registration**

Priority Substance

Potentially 4700 substances could be implicate based upon priority substance definition

Labelling and packaging requirements (Rules 33 & 34)

Some Priority Substances may require Registration – currently 748 substances are listed as Priority Substances for Registration in Schedule II

Certain Priority Substances may be added in Schedule X, and/or XI, and/or XII – transport and accident prevention of hazardous substances (Rule 16(3))

Schedule II – Substances to be Registered



Registration - Substances listed in Schedule II



Registration within 18 months after inclusion in Schedule II



Currently Schedule II contains 748 substances.

Deadline coincides with Initial Notification period



Technical Dossier needs to be prepared.



Chemical Safety Assessment (report) for > 10 TPA.



Registration fee is applicable – Company Size & Tonnage



Option to jointly submit the registration



Update Technical Dossiers - within 60 days of any change or revision in information



Technical Completeness of Dossier - within 60 days



Import of Priority substances requires to notify Authority 15 days before importation. (Rule 27)

Comparison between EU-REACH & ICMSR

EU REACH	ICMSR
Pre-registration (free)	Notification (fees apply)
Substance details, tonnage and company	Additionally: Uses, Downstream Users, Spectra, Hazard Class, SDS
Tonnage and data updates	Annual reports for all Substances
Registration of all Substances	Registration of Schedule II Substances only
Tonnage-specific deadlines	Common deadline (all tonnages)
Substances: SVHC, CoRAP, Restriction, Authorisation	Substances – Priority, Schedule II, Hazardous, Restriction & Authorization

Compliance Tips



- Set up a regulatory team
- Prepare an Inventory of substances being handled
- Identify the quantity placed in India
- Initiate communication with downstream users
- Update SDS in accordance with GHS Rev. 8
- Stay updated on the ICMSR
- Hold internal training activities on the ICMSR
- Follow up on the substance list: Substances to be registered (Schedule II), Restricted or Prohibited Substances (Schedule VI) and Hazardous Chemicals (Schedules X, XI and XII)

Thanks!

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CIRS Service



EU REACH



UK REACH



China Chemical Management



Korea REACH



Taiwan TCSCA



Global GHS



Training & Testing

Why CIRS



4000+ global SDS & Label every year



3000+ K-REACH pre-registration



2000+ EU REACH registration



2000+ China REACH typical notification



Designed TPR(Third Party Representative) service



Full one-stop compliance service in China



Customized on-site/online training service



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