

Latest Update on India's Draft Chemical Regulation

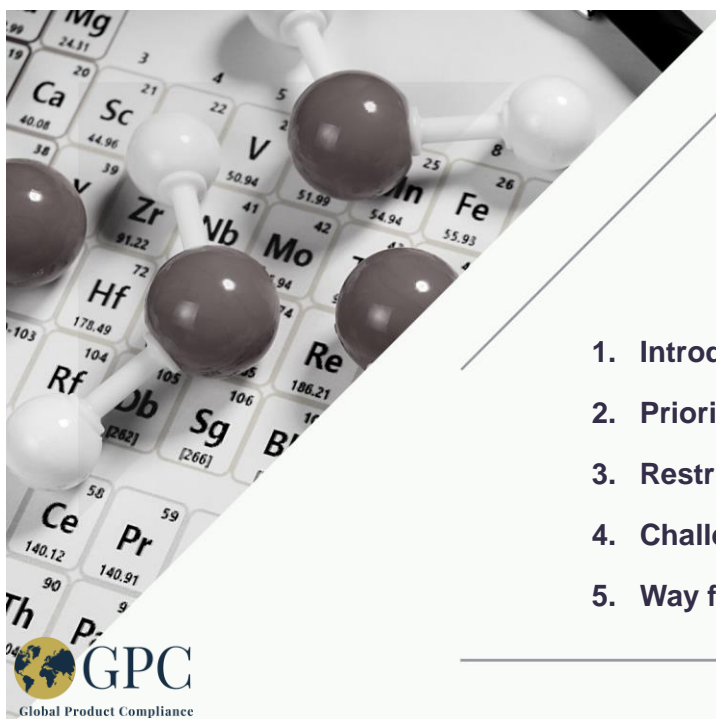
Indian Draft Chemicals (Management & Safety) Rules 20XX (ICMSR)



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Summary of Topics

1. Introduction to Draft ICMSR Rules
2. Priority substances
3. Restricted and hazardous substances
4. Challenges with Current Draft
5. Way forward for Companies

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Introduction to Draft ICMS Rules

Legal basis
 Scope
 Organization
 Obligation to notify
 Notification

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Implementing Organizations

Indian National Chemical Authority (INCA) has 3 key organs

- Steering Committee (16 Govt. officials)
- Scientific Committee (10 members + 5 co-opt members)
- Risk Assessment Committee (8 members and 4 co-opt members)

Chemical Regulatory Division

Chemistry Unit
Toxicology Unit
Chemical Accident Unit
Packaging & Labeling Unit

Techno-legal Unit
Priority Substance Unit
Information Technology Unit
Socio-Economic Unit



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ICMSR

- Chapter I – Definition, Objectives & Scope
- Chapter II – 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



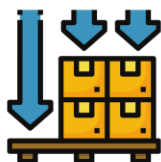
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Who can notify/register substance?



Manufacturer



Importer



**Authorized
Representative
with legal entity in India**

Authorized Representative

Authorized Representative has similar function as “Only Representative” in EU-REACH & K-REACH.

Foreign Manufacturer of

Substance	Substance in Mixture	Priority Substance in Article
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Shall appoint an Indian Legal entity to comply with ICMS Rules on its behalf

All substances if not exempted: Notify (1/2)

- 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
 - New substance or Existing substance
 - 60 day prior to placing would submit Notification

All substances if not exempted: Notify (2/2)

- Notification is not free
- Annual Report – within 60 days (29th Feb. / 1st March each year)
- Indian Inventory – Register of Notified Substances
- Notification check & complication → Certificate of Notification

Notification Data Required

- 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

- Details of Notifier:
 - Name, address, phone, email of the Notifier
 - Name, address, phone, email of the person authorised to submit Notification
 - Details of foreign manufacturer, if the Notifier is an Importer or Authorised Representative
 - Location of the production and own use site(s), as appropriate
- 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.
- List all impurities with more than 1.0% but less than 10% (w/w) concentration
- For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), give the following details:
 - Structural representation of the constituents
 - Reaction scheme (including the identity of the reactants and the reaction type)
 - Process output (including identity of the precursors, the technology (method of preparation; process terms) and the typical composition)
- Chemical Structural Details
 - Molecular wt.
 - Simplified Molecular Input Line Entry System (SMILES)
 - Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - Spectral data:
 - High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
 - Infra Red spectra
 - Ultra Violet-Vis Spectrophotometer – spectra
 - Nuclear Magnetic Resonance
- Hazard Classification of the Substance (according to eighth revision of UN-GHS)
- Chemical uses
- Name of known Downstream Users (at least top 3; will be kept confidential)
- Actual quantity per annum in TPA (will be kept confidential under all circumstances)
- 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.)

Source: 5th draft of ICMS Rules

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Notification Fees

Tonnage band of Substance	MSME	Large
1 – 10 TPA	10,000 ₹ (~140 \$)	25,000 ₹ (~350 \$)
10 – 100 TPA	30,000 ₹ (~420 \$)	75,000 ₹ (~1050 \$)
100 – 1000 TPA	80,000 ₹ (~1120 \$)	2,00,000 ₹ (~2800 \$)
> 1000 TPA	2,50,000 ₹ (~3500 \$)	6,00,000 ₹ (~8400 \$)

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Notification Certificate

Part A- Notification Certificate

Notification Certificate	
issued under Rule 8 of the Chemicals (Management & Safety Rules), 20xx	
Name of the Notifier:	
Name of the Substance:	
Chemical Composition of Substance:	
Tonnage Band that the Substance falls under:	
Notification Number:	
Notification Date:	
Comments:	
Issued by Head, Chemical Regulatory Division Petroleum and Explosives Safety Organisation	

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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**

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Obligations of Downstream Users (DU)

- Procure Notified or Registered substances as applicable
- Verify uses - included by the supplier – in Notification / Reg.
- Share uses with supplier to ensure its inclusion
- Confidential Uses / Uses Not included → DU to Notify
- DU to submit SDS for such uses – to Division
- May opt to register if substance is in Schedule II Substance



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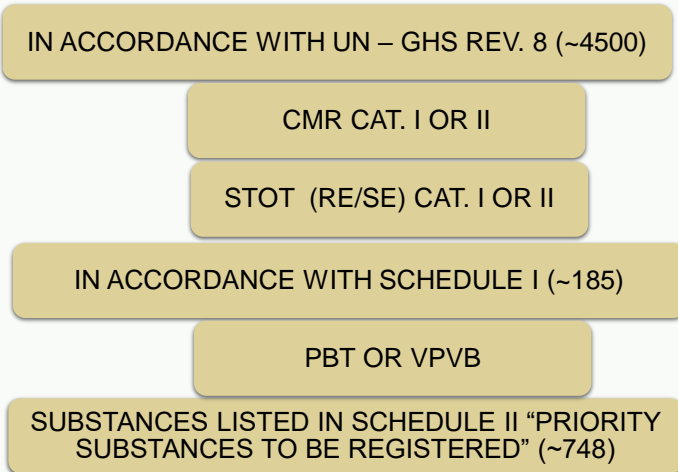
Priority Substances

Rule 2(hh) of Draft ICMS Rules

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Priority substances



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Priority substances

-  Potentially 4700 substances could be implicate based upon priority substance definition
-  labeling and packaging requirements (Rules 33 & 34)
-  Import of Priority substances requires to notify Authority 15 days before importation. (Rule 27)
-  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))

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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.

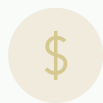
*Deadline coincide with
Initial Notification
period*



Technical Dossier
needs to be prepared.



Chemical Safety
Assessment (report) for
> 10 TPA.



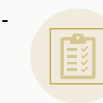
Registration fee is
applicable – Company
Size & Tonnage



Option to jointly
submitting the
registration,



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



Technical
Completeness of
Dossier - within 60
days



Restricted and Hazardous Substances

Schedule X, XI, XII of Draft ICMS Rules

Restricted Substances (1/2):

- Registration data and CSR to be assessed to check for substances that may meet the criteria for:
 - Hazardous Substance
 - Restriction
 - Prohibition

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Restricted Substances (2/2):

- Restriction or Prohibited Substances Listed in Schedule VI
- Hazardous Substances be Listed in Schedule X, XI and XII
- Authorization for Restricted Substance is possible (4 + 4 years)
- Authorization Fee 1 M INR (14,000 \$)

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Specific Requirements: Hazardous Substances & Installations

-  Transport –Tracking & Communication System; Labeling,
-  Safety Audit of installation – within 6 month; every 2 years (Sch. XI & XII)
-  Site Safety Report – Steps in accident prevention; Provide information, training, equipment and antidotes – for safety employee / implicated. (Sch. X, XI, XII)
-  Isolated storage and quantity Thresholds (Schedule XI & XIII)
-  Onsite / off-site Emergence Preparedness Plan within 3 months; (on-site - mock drill every 6 month)
-  Notification of Accident within 24 hrs; report within 72 hrs.

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Fee Structure

Registration Fee

Tonnage band of Substance	MSME	Large
1 – 10 TPA	15,000 ₹ (~210 \$)	37,000 ₹ (~518 \$)
10 – 100 TPA	45,000 ₹ (~630 \$)	1,12,000 ₹ (~2568 \$)
100 – 1000 TPA	1,20,000 ₹ (~1680 \$)	3,00,000 ₹ (~4200 \$)
> 1000 TPA	3,75,000 ₹ (~5250 \$)	9,00,000 ₹ (~12600 \$)

Other Fee

Confidentiality claim	5,000 ₹ (~75 \$)	1,00,000 ₹ (~1400 \$)
Authorization	10,00,000 ₹ (~14000 \$)	10,00,000 ₹ (~14000 \$)
Filing an Appeal	10,000 ₹ (~140 \$)	1,00,000 ₹ (~1400 \$)

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Suggested Changes for 6th Draft

Regulatory Submissions:

1. A realistic registration timeline for initial Schedule II list, proposed to be extended from 18 to 30 months.
2. Clarity on details of "Robust Study Summary" (RSS) and tonnage specific data requirements.
3. Clarity on registration requirements to existing listed hazardous substances (Schedule X, XI, and XII) in addition to the Schedule II substances.
4. Explicit mentioning of the SDS language in the regulation, priority wise English and the local language.

Substance Specific:

1. Clarification of Polymer Registration – multiple Mol. Wt. would have same CAS and the toxicity profile may vary. If its in Schedule II then we may need Registration. In EU, UK, Korea, Turkey - Monomers and additives of polymers are to be registered (Notified) instead of a Polymer.
2. Suggestion of lower data requirements for Intermediate (for > 1000 TPA) because of no exposure to general public.
3. Clarity on Nano-forms at a later date at least when registration is operational.

Logistical and Administrative:

1. Update on Scientific and Risk Assessment Committee members to avoid conflict of interest (E.g., from GLP labs).
2. Update on the definition of an Authorized Representative (AR), possibly avoiding minimum levels of net worth and focusing more on experience and financial securities through other means.
3. Proposal on updating the non-compliance penalty from per day to within a period of 1-2 months.
4. Suggestion for notification of New-substances – 60 days prior to placing in the Indian Market.
5. Defining specific data requirements for the annual reporting template.

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Comparison EU-REACH & ICMSR



EU REACH

- Pre-Reg.
- Pre. Reg. Free
- Sub. Details, Tonnage, Company
- Tonnage and data update
- Reg. of all substances
- Tonnage specific deadlines
- Substances – SVHC, CoRAP, Restriction; Authorization

ICMSR

- Notification
- Notification fee
- Additionally Uses , DUs, Spectra, Hazard Class, SDS
- Annual Report of all Notified
- Reg. only Sch. II substances
- All tonnages same deadline
- Substances – Priority, Sch. II, Hazardous, Restriction & Authorization



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Way Forward

Preparedness for Businesses

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Substance Category & Regulatory Responsibility

Regulatory Process	All Substances	Priority Substances	Priority Substances to be Registered	Hazardous Substances
Definition / Criteria	2(1)(ss)	2(1)(hh)	2(1)(hh)	2(1)(l)
Listed in	Register of Notified substances		Schedule II	Schedule X, XI, XII
Process of Inclusion in Schedule	8(11)	8(12) & 8 (13)	8(12) & 8 (13)	16 (3)
Notification (Rule 8)	Yes	Yes	Yes	Yes
SDS (UNGHS 16 Point)	Yes	Yes	Yes	Yes
Compliance Status	Notification Certificate	Notification Certificate	Registration Certificate	Registration Certificate
Packaging & Labeling requirement	No	Yes	Yes	Yes
Import Notification (authority)	No	Yes	Yes	Yes
Registration Requirements	No	No	Yes	Yes
Technical Dossier required	No	No	Yes	Yes
CSR / ES required	NO	No	Yes	Yes
Evaluation & Restriction	No	No	Yes	Yes
Storage capacity Threshold	No	No	No	Yes
Safety Audit	No	NO	No	Yes
Site Safety Report	No	No	No	Yes
Emergency Preparedness	No	No	No	Yes

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“GPCgateway.com”

- “GPCgateway.com” – remains a most updated source of info on the Rules and other regulations and is available for free to all uses.

The screenshot shows the GPCgateway.com website with a dark blue header and a white main content area. The main headline reads "Final Draft of India REACH (CMSR) is out now!". Below this, it states "5 new updates" and lists several key points: "All substances to be notified", "National Chemical Authority to be established", "1st list - 750 priority substances to be registered", and "Pre-Import notification required for hazardous substances". A sidebar on the right lists "GPC Worldwide" with links to various regional offices including Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, Switzerland, Taiwan, Thailand, Turkey, UK, USA, and Vietnam.

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Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



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