Draft Indian Chemical Management and Safety Rules (CMSR), 20xx (India-REACH)

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About GPC
Global Product Compliance (GPC) specializes in Global Regulatory Compliance Solutions across sectors globally. SSS Europe, a familiar name in chemical regulatory and compliance services now formally belongs under the umbrella of GPC Holding Sweden.

Since 2008, we have emerged as one of the leading names among Global Regulatory Compliance Service Providers with Representation services in Europe, Asia and Middle East for respective chemical regulations.

Our over 1000 Happy Clients are a testimony to the great rapport we share with them and the fine quality that we offer in our services. This is also reflected in the fact that we have about 99% customer retention.
AGENDA

India CMSR – India REACH (5th Draft - 24 Aug 2020)

- GPC in brief and GPC’s engagement in Indian CMSR
- ICMSR – Key words, Objective, Scope, and Authorities
- Chapters & Related Schedules
- Timeline and Obligations under ICMSR
- Fees : Notification, Registration
- Actionable for PSCI members (Overseas and Indian) & Importers
- GPC : Your Knowledge Partner toward ICMSR compliance
- Interaction (Q&A)
Global Product Compliance (GPC)

- Indian Chemical (Management and Safety) Rules (ICMSR)
- EU-REACH
- Korea-REACH
- Eurasia REACH
- Turkey REACH (KKDIK)
- UK-REACH
- Taiwan Regulation (TCSCA)
- Chemical Regulations in USA, Canada, Australia, Thailand, China, Japan & Brazil.
- Cosmetics Regulation (EU, India, USA).

1000+ Happy Clients.
99% Customer retention
172+ companies opted to switch over to GPC
Global Product Compliance (GPC)

Services
- Registrations & Notifications
- Global Regulatory Compliance & Status Assessment
- Substance & Dossier Evaluation Process Management
- Lead Registration activity & Technical dossier preparation
- Toxicological assessment & Dossier updates
- Contract Study Management & Monitoring
- Compliance Verification & Certificates
- REACH & CLP compliant SDS & Extended e-SDS
- SDS translations in over 30 languages

Services – Key facts
- Managed portfolio of 9000+ substances.
- Registered 1200+ substances.
- Lead Registration & consortia management of 400+ substances.
- 9000+ pre-registrations and notifications within chemical and cosmetic regulations, globally.
- Authored 4200+ REACH & CLP compliant SDSs and 320+ e-SDSs.
- Extensive network of OECD-GLP certified CROs.
- ‘Supply Chain Communication Portal’ for seamless regulatory communication and due diligence – between supplier, buyer, and OR. The portal is used by 4000+ users.

GPC provide regulatory intelligence to industry and prepare industry for the compliance requirements & related challenges!
GPC Engagement with Indian CMSR

2010
Ministry of Commerce / CHEMEXCIL engaged GPC for report on regulatory status of EU REACH regulation and its impact on Indian Industry Proposed Road-map for Indian Chemical Regulation

2011-2018
GPC was actively engaged with Ministry of Commerce and Dept. of Chemicals and Petrochemicals on the development of Draft National Chemical Policy

July 2018
GPC as a member of CII’s National Chemical Committee, was engaged in drafting a proposal for chemical rules and submitted it to the government

Jan 2019
GPC was asked to present the draft Chemicals Rules in National Standard’s Conclave organized by CII and Ministry of Commerce

May 2019
Ministry of Commerce later formed a technical committee to review the regulation, wherein GPC and CII were the only non-governmental representative. The technical committee adapted GPC’s draft of the proposed chemicals rules as an official draft

2020
Since Mid 2019, draft is being updated and has been circulated for the comments by the industry bodies, on 4th draft in March 2020. After stakeholder’s consultation meeting on 11th May 2020, an updated draft was released on 7th Sept 2020 (5th Draft)
## ICMSR – Key words, Objective, Scope, Authorities

<table>
<thead>
<tr>
<th>Key Words</th>
<th>Substance ; Substance in Mixture; Mixture; Articles; New Substance, Existing Substance; Priority Substance ; Hazardous Substance; Chemical Accident; Intermediates ; Isolated Storage ; Industrial Activity; Occupier ; Manufacturer ; Importer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective &amp; Scope</td>
<td>Notification, Registration and Restrictions, or prohibitions, as well as labelling and packaging requirements related to the Use of Substances..... Placed or intended to be Placed in Indian Territory</td>
</tr>
<tr>
<td>Provide safety procedures for the Manufacture, handling and Import of Hazardous Chemicals and preparedness and management of Chemical Accidents; Ensure a high level of protection to human health and the environment.</td>
<td></td>
</tr>
<tr>
<td>Authorities</td>
<td>The National Chemical Authority with 4 key organs to implement the Rules:</td>
</tr>
<tr>
<td></td>
<td>• Steering Committee</td>
</tr>
<tr>
<td></td>
<td>• Scientific Committee</td>
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<tr>
<td></td>
<td>• Risk Assessment Committee</td>
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<tr>
<td></td>
<td>• Chemical Regulatory Division</td>
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<tr>
<td></td>
<td>Chemistry Unit</td>
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<tr>
<td></td>
<td>Toxicology Unit</td>
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<tr>
<td></td>
<td>Chemical Accident Unit</td>
</tr>
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<td></td>
<td>Packaging &amp; Labeling Unit</td>
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<tr>
<td></td>
<td>Techno-legal Unit</td>
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<td></td>
<td>Priority Substance Unit</td>
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<td></td>
<td>Information Technology Unit</td>
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<td></td>
<td>Socio-Economic Unit</td>
</tr>
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## India Chemicals (Management & Safety) Rules

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<th>Title</th>
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<td>I</td>
<td>Definitions, Objective &amp; Scope</td>
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<tr>
<td>II</td>
<td>National Chemical Authority</td>
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<tr>
<td>III</td>
<td>Notification Registration &amp; Restrictions on Use</td>
</tr>
<tr>
<td>IV</td>
<td>Safety &amp; Accident Preparedness</td>
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<td>V</td>
<td>Labelling &amp; Packaging</td>
</tr>
<tr>
<td>VI</td>
<td>Miscellaneous (Penalties and Enforcement)</td>
</tr>
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</table>
### India Chemicals (Management & Safety) Rules

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>PBT &amp; vPvB Assessment Criteria</td>
</tr>
<tr>
<td>II</td>
<td>List of Priority Substances required to be Registered (750 Subs.)</td>
</tr>
<tr>
<td>III</td>
<td>Concerned Authorities</td>
</tr>
<tr>
<td>IV</td>
<td>Substances Exempted for the purpose of Chapter III and V</td>
</tr>
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<td>V</td>
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<td>VI</td>
<td>Restricted or Prohibited Substances (Phosgene as on date, will be added later...)</td>
</tr>
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<td>Contents of Technical Dossier</td>
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<td>Format for Chemical Safety Report</td>
</tr>
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<td>IX</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>X</td>
<td>Hazardous Chemicals (669 Substances, will be added latter...)</td>
</tr>
<tr>
<td>XI</td>
<td>Isolated Storage At Installations Other Than Those Covered By Schedule XIII (30 Subs.)</td>
</tr>
<tr>
<td>XII</td>
<td>List of Hazardous Chemicals for Application of Chapter IV (Safety &amp; Accident Preparedness) (179 Subs. + Flammable Gas &amp; Liquids)</td>
</tr>
<tr>
<td>XIII</td>
<td>Industrial Installations (Alkylation, Condensation, Hydrolysis, Sulphonation &amp; so on ...) 20 identified</td>
</tr>
<tr>
<td>XIV</td>
<td>Information to be Furnished by the Occupier</td>
</tr>
<tr>
<td>XV</td>
<td>Details to be Furnished in the Off Site Emergency Plan</td>
</tr>
<tr>
<td>XVI</td>
<td>Information to be Furnished Regarding Notification of a Chemical Accident</td>
</tr>
<tr>
<td>XVII</td>
<td>Information in Labelling</td>
</tr>
<tr>
<td>XVIII</td>
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<tr>
<td>XIX</td>
<td>Fees and Fines Payable</td>
</tr>
</tbody>
</table>
Timeline & Obligation under ICMSR

**Notification** Of Substances ≥ 1 ton/year

**Registration** of Schedule II Chemical Substance (750) ≥ 1 ton/year

**Evaluation** Of files and Substances

**Restriction & Prohibition** Of Unacceptable Substances

**Authorization** Of Substances of concern by Committee

**Annual Reporting** - No later than 60 days after the end of each calendar year

**Information in the supply chain**

**Chemical Properties & Uses**: Up & down - Supply chain
Timeline & Obligation under ICMSR

Initial Notification Period

- **Qty > 1 T/year**
  - Start date: Say April 2021
  - End date: Sept 2022

- **1 year**
- **6 months**

**Timing + Schedule + Volume**

- **New substances ➔ Notify 60 days prior to placing in market**
- **Registration of substance in Schedule II (750 as on date)**
- **For Qty <1 T/year Reg. requirements based on Scientific committee & Divisions recommendations**
- **Qty > 1 Ton / year**

**Annual Reporting**
- No later than 60 days after the end of each calendar year

**Missed Notification period – Substance existing: 60 days prior to placing**

- **Rule into force 20xx**

- Substance in Schedule II includes Carcinogenic, Toxic for reproduction, Endocrine Disturbers

PSCI VIRTUAL SUPPLIER CONFERENCE SEP-OCT 2020

@PSCInitiative
## Fees: Notification & Registration

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8 (5)</td>
<td>Notification by tonnage band</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-10 TPA</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100-1000 TPA</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 TPA</td>
<td>250</td>
</tr>
<tr>
<td>2</td>
<td>10 (10)</td>
<td>Registration by tonnage band</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-10 TPA</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100-1000 TPA</td>
<td>120</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 TPA</td>
<td>375</td>
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<tr>
<td>3</td>
<td>16 (5)</td>
<td>Request for authorization for use of a restricted substance</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1000</td>
<td>1000</td>
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<tr>
<td>4</td>
<td>17 (3)</td>
<td>Request for confidentiality</td>
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<tr>
<td></td>
<td></td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>19 (4)</td>
<td>Filing an appeal</td>
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<tr>
<td></td>
<td></td>
<td>10</td>
<td>100</td>
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</tbody>
</table>
### Fees : Update Notification & Registration

Approx.: Fees for Updating tonnage band in notification and registrations  
(Rs. '000)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other entities</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Updating tonnage band</td>
<td>From 1- 10 TPA To 10 - 100 TPA</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 1- 10 TPA To 100 - 1000 TPA</td>
<td>70</td>
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<tr>
<td></td>
<td></td>
<td>From 1- 10 TPA To &gt; 1000 TPA</td>
<td>240</td>
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<tr>
<td></td>
<td></td>
<td>From 10- 100 TPA To 100-1000 TPA</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 10- 100 TPA To &gt;1000 TPA</td>
<td>220</td>
</tr>
<tr>
<td></td>
<td></td>
<td>From 100- 1000 TPA &gt; 1000 TPA</td>
<td>170</td>
</tr>
</tbody>
</table>
## Fees: Joint Registration

### Approx.: Fees for Joint Registration per Registrant (RS. '000)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Rule</th>
<th>Tonnage band</th>
<th>Payable entity (MSMEs)</th>
<th>Payable by all other Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 (10)</td>
<td>1-10 TPA</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 TPA</td>
<td>30</td>
<td>75</td>
</tr>
<tr>
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<td></td>
<td>100-1000 TPA</td>
<td>80</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;1000 TPA</td>
<td>250</td>
<td>600</td>
</tr>
</tbody>
</table>

Joint Registration is valid for the same substance !!!
Actionable for PSCI members

- Indian Manufacturer / Importer / DU: Follow guideline and be a Notifier

- Overseas Manufacturer:

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

Foreign Manufacturer of

Substance

Substance in Mixture

Priority Substance in Article

Foreign Traders may not appoint an Authorized Representative

Shall appoint an Indian Legal entity to comply with ICMS Rules on its behalf
Actionable for PSCI members - Notification

- Notify all substances that are placed in Qty > 1 TPA
- Notification is **not Free**
- **Key data required:** Spectra, Hazard Classification, Uses, DU if any, Tonnage Band, Storage Capacity, SDS (Rule 9(2))
- **Annual update by 1st March each year** – tonnage (actual); new/change information; if tonnage change (fee difference)
- **Registration within other regulations / Acts** – are also required to Notify with ICMS Rules
- **Late Notification**
  - New Substance (60 days prior to placing)
  - Existing Substance: if missed notification window – 60 days prior to placing it in market.
Notification Process:

- Substance Notifier
- Submit Notification
- Chemistry unit (Authorities)
  - Submit Requested Additional Information
  - Information satisfactory
  - No CBI Check Request
  - CBI Check If Any
    - More Information Required
    - Techno Legal Unit Cleared CBI Application

- Request for information
  - 60 days Prior to placing in Market
  - New Chemical

- Substance entered into Notified Substance Register
- Notification Number Assigned & Certificate Released
- Continue placing substance in Market
- Submit in 30 days
  - More Information Required
  - CBI Check If Any
  - Techno Legal Unit Cleared CBI Application
  - Substance entered into Notified Substance Register
  - Notification Number Assigned & Certificate Released
  - Continue placing substance in Market
  - Submit in 30 days
Substances that are notified within the “Initial Notification Period” are considered as Existing Substances.

All substances that are not notified in the Initial Notification Period are considered as New Substances.
Evaluation Process: Post Notification

1. Substance in Notified Substance Register
2. Taken for Evaluation
3. Priority Substance Unit (Authorities)
4. For Addition / Deletion of substance to Schedule II
5. Final Recommendation to Central Government
6. Schedule II Updated
7. Goes for Public Consultation
8. Inputs Public Consultation
9. In 90 days
10. Recommends Steering Committee

Steering Committee

Check Potential Risk on Substance Use

Evaluation of collected Data

Substance Data Availability Check
Actionable for PSCI members - Registration

Registration - Substances listed in Schedule II
Priority Substances

Registration within 18 months after inclusion in Schedule II

Currently Schedule II contains 750 substances.

Technical Dossier needs to be prepared.

Chemical Safety Assessment (report) for > 10 TPA.

Exposure Scenario 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

Joint Registration is valid for the same substance!
Actionable for PSCI members: Registration process

1. Substance for Registration > 1Ton/Year
   - Submit Tech. Dossier
   - Schedule II Chemical

2. Toxicology Unit
   - Request for information
   - Preliminary Checks
   - CBI Check if any
   - More Information Required

3. Information Satisfactory
   - Techno Legal Unit
   - Cleared CBI Application

4. Toxicology Unit
   - Evaluates submitted Data
   - Data Satisfactory
   - Registration Number & Certificate Released

5. Update Tech. dossier within 60 days for new information or changes if any
   - Submit Requested Additional Information (60 days)

6. 18 month from date of Rule coming into Force

7. Evaluation of submitted Data
   - Registration Number & Certificate Released

8. Actionable for PSCI members: Registration process
Currently 750 substances are listed as Priority Substances in Schedule II. – Notify & Register

Schedule II will be updated from time to time

labeling and packaging requirements (Rules 33 & 34)

Import of Priority substances: Inform Authority 15 days before importation. (Rule 27)

Certain Priority Substances may qualify as – Hazardous Substances (Rule 16(3))
Substances that are Listed in Schedule VI: Restricted or Prohibited Substances

As on today only one substance restricted: Phosgene (carbonyl chloride)
**Actionable for PSCI members: Evaluation & Restriction Process**

- **All Registered Substances**
  - Evaluation Based on Available Data
    - Risk Assessment including hazard identification, hazard characterization, exposure assessment, and risk characterization.

- **Priority Substances Unit**
  - Evaluated by

- **Recommends**
  - Risk Assessment Committee & Steering committee

- **Substance Identified for Restriction**

- **Submit Request for Authorization for Restricted Use**

- **If Deemed Fit; Authorization Granted for 4 Years**

- **Upon Re-application: Extension of Authorization granted for additional 4 years.**

**Inclusion or Deletion to Schedule X, XI and XII**

**Restriction on a Priority Substance has been notified**

**Prohibit use of substance**

**Public Consultation within in 90 day by Steering Committee prior to recommending the Central Government!**

**Poses an unacceptable risk to human safety or the environment**
**Actionable for PSCI members – Transported Intermediate**

- **Transported Intermediates** - Substances listed in Schedule II
- **< 1000 TPA** (Only Phys - Chem data in Technical Dossier)
- **> 1000 TPA** (full Registration and Chemical Safety Report)

- **Intermediates not in Schedule II**
- **No Registration obligation**
- **Only Notification obligation**

Intermediate substance not included in Schedule II are exempted from Registration:

**But to be Notified!**
Currently 669 substances are listed as Hazardous Chemical List in Schedule X. -- Notify

Schedule X will be updated from time to time

Labeling and packaging requirements (Rules 33 & 34)

Provide evidence to authorities that they have identified the Chemical Accident hazards
  Adequate steps taken to prevent accidents & to limit its impact

Evidence shall be provided within 30 days of commencement of the activity or within 30 days of coming into force of these Rules, whichever is later.

Obtain an Acknowledgement from Authority with 60 days
Transport – Tracking & Communication System; Labeling, give prior intimation the State Pollution Control Boards

Safety Audit of installation – within 6 month; every 2 years

Site Safety Report (New industrial activity - 90 days before) – Steps in accident prevention; Provide information, training, equipment and antidotes – to Employees; and Get Approval from Authorities

Isolated storage and quantity Thresholds (Schedule XI & XIII - industrial installations)

Onsite / off-site Emergency Preparedness Plan within 3 months; (on-site - mock drill every 6 month)

Notification of Accident within 24 hrs.; report within 72 hrs. Report on preventive action with 6 months of accident
Do not Miss Notification & Registration Deadline once The Rule is into Force!
For more information about the PSCI please contact:

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+44 (0) 7794 557524

**About the Secretariat**
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.