

Updates of the Draft Indian Chemicals Management and Safety Rules (India REACH)

Know your obligations and start preparing



Vaibhav Diwan, PhD
Global BDM, GPC Group
vdiwan@gpcregulatory.com



NextGen Chemicals & Petrochemicals Summit 2022

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About GPC



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We offer regulatory representative and compliance management services globally.



8 offices worldwide & 2 laboratories



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25% PhDs, 75% Master's and Post Graduate Degree



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Specialized Sectors

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- **Biocides & Disinfectants**
- **Chemicals**
- **Cosmetics**
- **Food Contact Materials**
- **Fertilizers & Bio-stimulants**
- **Medical Devices**
- **Plant Protection Products**



An overview of Chemical Regulations

Implemented

Transitional / Draft

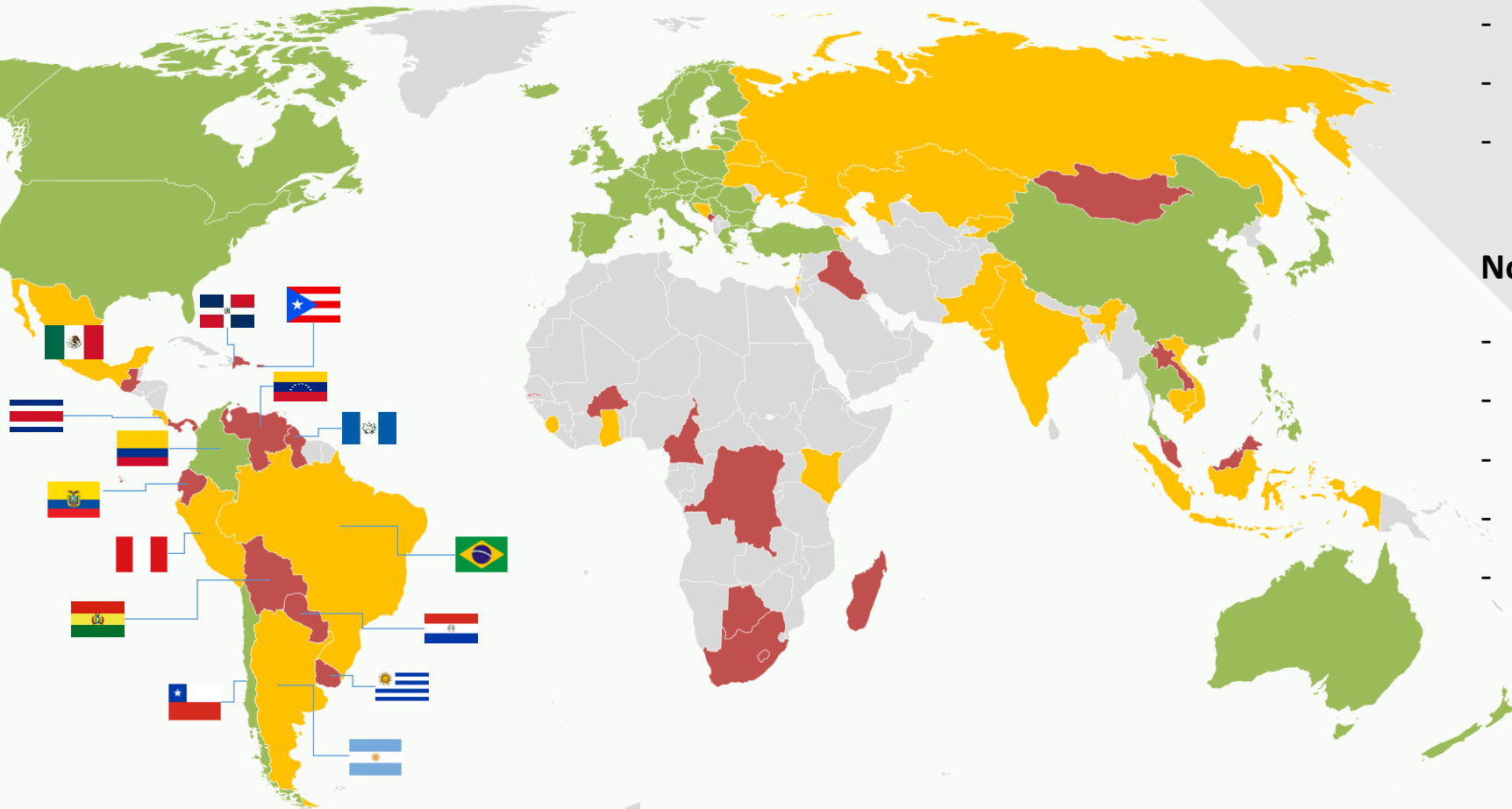
No legislation

In Development:

- Argentina
- Brazil
- Costa Rica
- Mexico
- Peru

No Legislation:

- Bolivia
- Dominican Republic
- Ecuador
- El Salvador
- Guyana
- Panama
- Paraguay
- Porto Rico
- Uruguay
- Venezuela



Content



GPC's engagement with ICMSR (India REACH)

Chemical Management in India

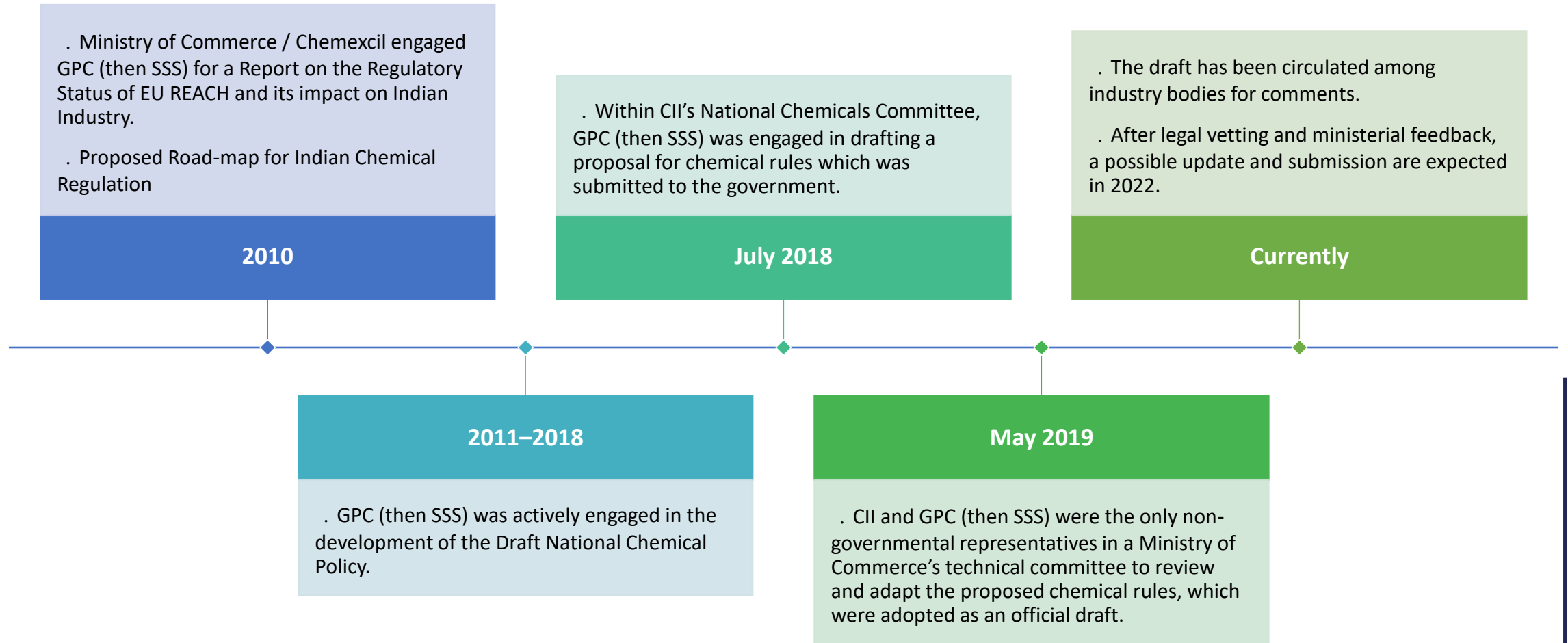
Introduction to the 5th Draft of ICMSR – Schedule, Scope, organizations

Key compliance obligations:

- Notification
- Intermediates
- Priority Substance
- Registration

Compliance Strategies for Companies

GPC – Engagement with ICMSR



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 |

Indian Chemicals Management and Safety Rules(ICMSR)

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

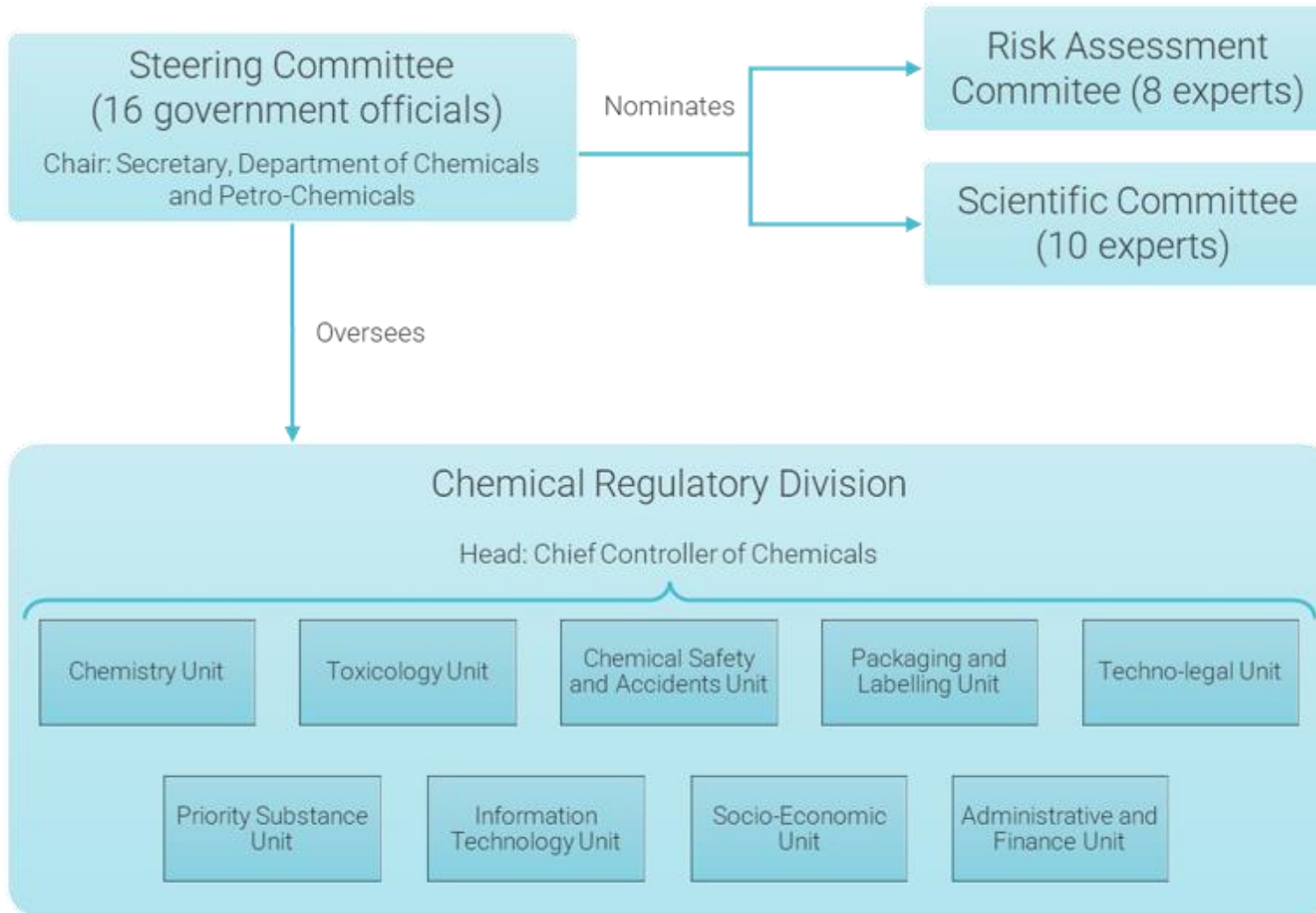
Schedules (I to XIX)

ICMSR - Schedules

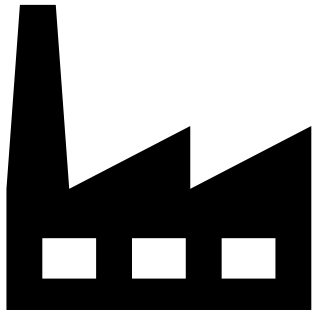
| | | | |
|------|---|-------|---|
| I | PBT and vPvB Assessment Criteria | XI | Isolated Storage at Installations Other Than Those Covered by Schedule XIII |
| II | List of Priority Substances required to be Registered | XII | List of Hazardous Chemicals for Application of Chapter IV |
| III | Concerned 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 | | |

Implementing Organizations

Indian National Chemical Authority (INCA)

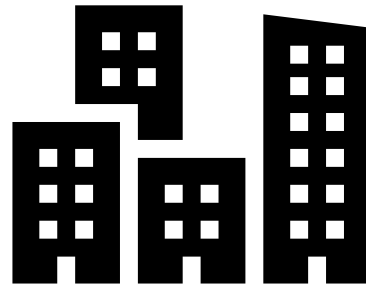


Roles under ICMSR and their obligations



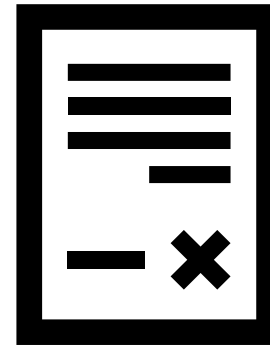
Indian Manufacturers

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



Indian Importers

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



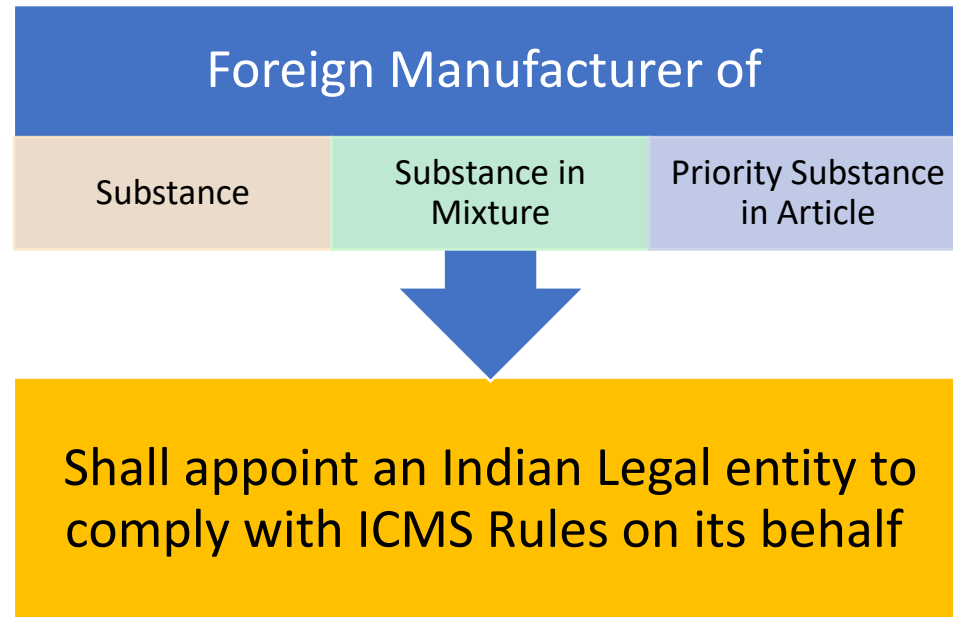
Authorized Representative (non-Indian manufacturer)



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.

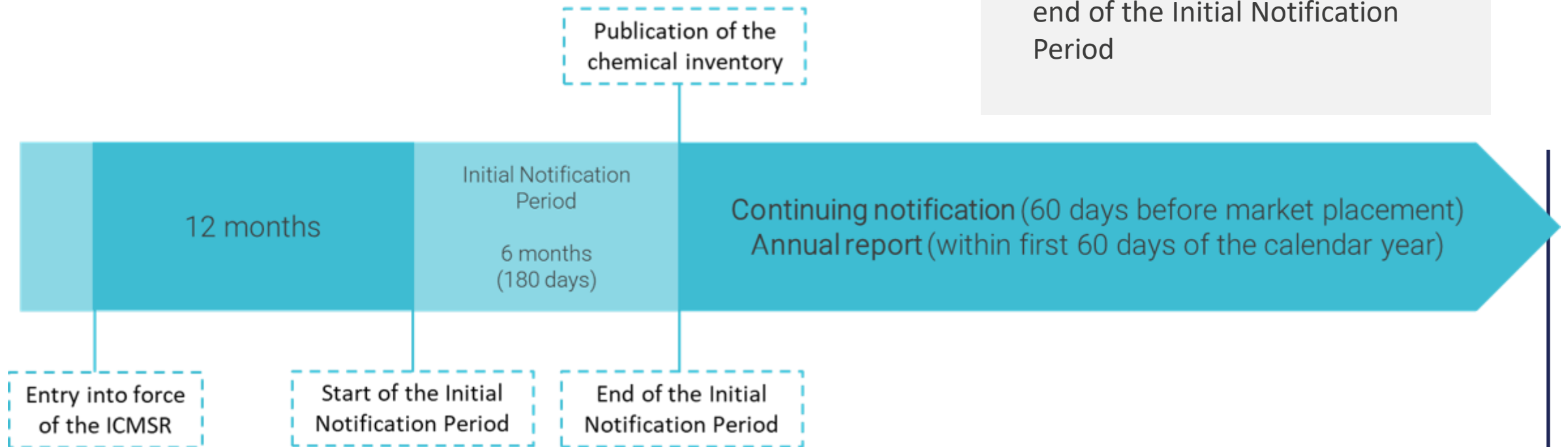
Key Compliance obligations

| | 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

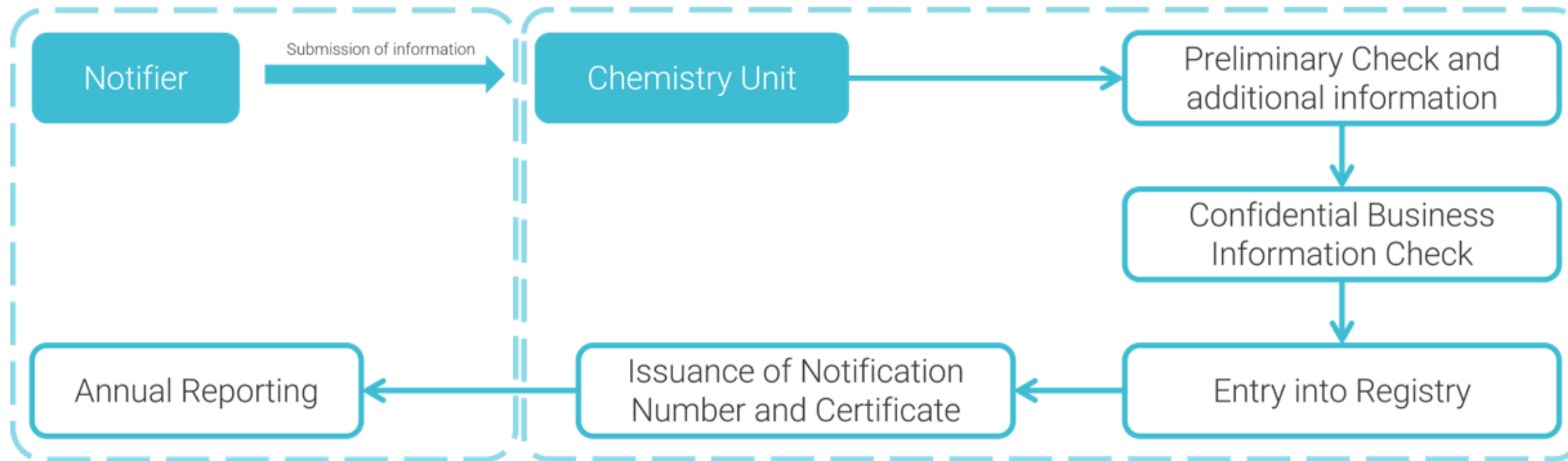
| S.No. | IUPAC Name | Common Name | CAS No. | Molecular structure | Isomer | % age Conc. |
|-------|------------|-------------|---------|---------------------|--------|-------------|
| | | | | | | |

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.)

Source: 5th draft of ICMS Rules

Notification Procedure



The ICMSR provides for the public availability of:

- Substance information
- Substance uses
- Substance classification

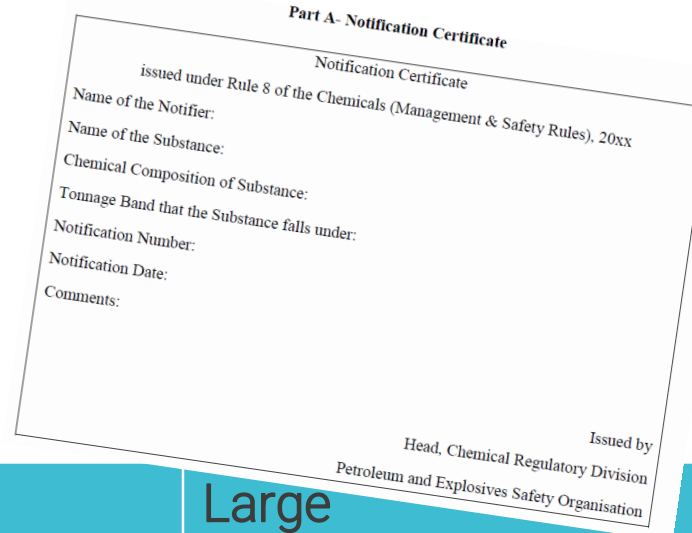
Confidentiality requests can be made on the basis of:

- 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 \$) |

Conversions current as of 14 April 2022

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 Substances



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

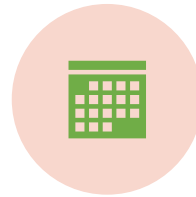


Certain Priority Substances may be added in Schedule X, and/or XI, and/or XII – transport and accident prevention of hazardous substances (Rule 16(3))

Schedule II – Substances to be Registered



Registration - Substances listed in Schedule II



Registration within 18 months after inclusion in Schedule II

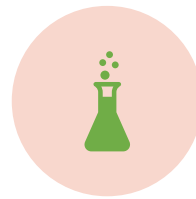


Currently Schedule II contains 748 substances.

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



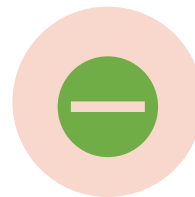
Option to jointly submit the registration



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)

Registration Fee

| Substance tonnage band | MSME | Large |
|------------------------|-----------------------|------------------------|
| 1 – 10 TPA | 15,000 ₹ (~196 \$) | 37,000 ₹ (~485 \$) |
| 10 – 100 TPA | 45,000 ₹ (~590 \$) | 112,000 ₹ (~1,470 \$) |
| 100 – 1000 TPA | 120,000 ₹ (~1,575 \$) | 300,000 ₹ (~3,936 \$) |
| > 1000 TPA | 375,000 ₹ (~4,920 \$) | 900,000 ₹ (~11,808 \$) |

Challenges of the Current Draft

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 |

Suggestions

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).
4. Explicit mentioning of the SDS language in the regulation, priority wise English and the local language.

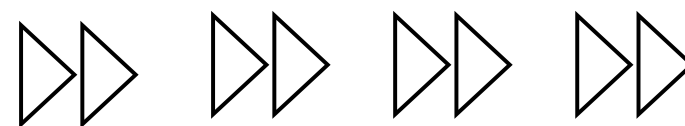
Substance Specific:

1. Clarification of Polymer Registration
2. Suggestion of lower data requirements for Intermediate (for > 1000 TPA) because of no exposure to general public.
3. Clarity on Nano-forms.

Logistical and Administrative:

1. 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.
2. Proposal on updating the non-compliance penalty.
3. Defining specific data requirements for the annual reporting.

Way forward for companies

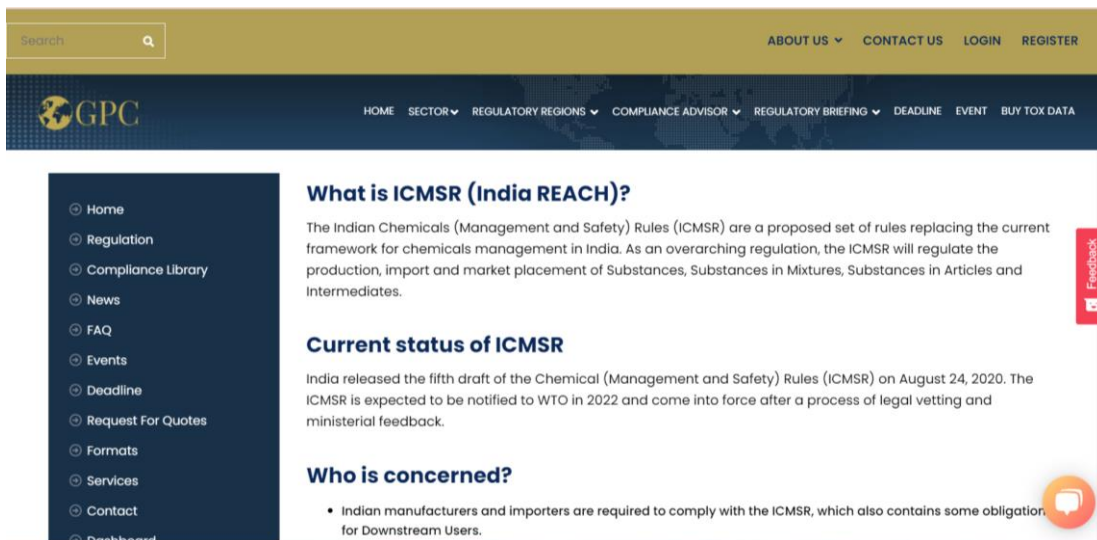


Compliance preparations

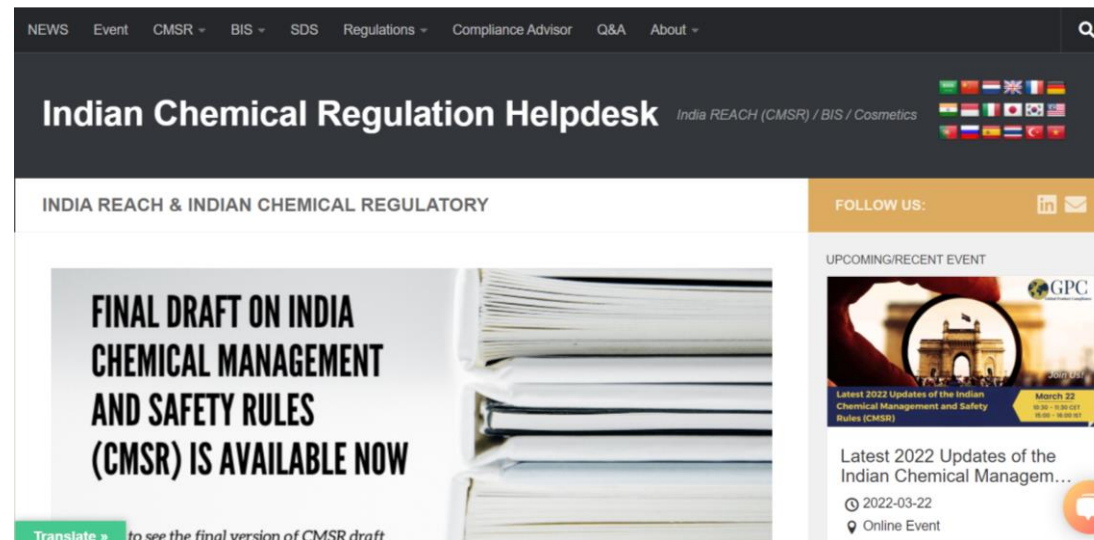
- Set up a regulatory team
- Prepare an Inventory of substances being handled
- Identify the quantity placed in India
- Initiate communication with downstream users
- Update SDS in accordance with GHS Rev. 8
- Stay updated on the CMSR
- Hold internal training activities on the ICMSR
- Follow up on the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

More information

- GPC gateway – Global Regulatory Intelligence Portal – www.gpcgateway.com
- ICMSR (India REACH) Helpdesk – www.indianchemicalregulation.com



The screenshot shows the GPC website home page. The top navigation bar includes a search box, a search icon, and links for ABOUT US, CONTACT US, LOGIN, and REGISTER. Below this is a dark blue header with the GPC logo and a menu: HOME, SECTOR, REGULATORY REGIONS, COMPLIANCE ADVISOR, REGULATORY BRIEFING, DEADLINE, EVENT, and BUY TOX DATA. A left sidebar contains a list of navigation items: Home, Regulation, Compliance Library, News, FAQ, Events, Deadline, Request For Quotes, Formats, Services, Contact, and Dashboard. The main content area features a section titled "What is ICMSR (India REACH)?" with a sub-section "Current status of ICMSR" and "Who is concerned?". A red "Feedback" button is visible on the right side of the content area.



The screenshot shows the Indian Chemical Regulation Helpdesk website. The top navigation bar includes links for NEWS, Event, CMSR, BIS, SDS, Regulations, Compliance Advisor, Q&A, and About. The main header reads "Indian Chemical Regulation Helpdesk" with a sub-header "India REACH (CMSR) / BIS / Cosmetics" and a row of flags. Below the header is a section titled "INDIA REACH & INDIAN CHEMICAL REGULATORY". The main content area features a large banner with the text "FINAL DRAFT ON INDIA CHEMICAL MANAGEMENT AND SAFETY RULES (CMSR) IS AVAILABLE NOW" and a "Translate" button. To the right, there is a "FOLLOW US" section with social media icons and an "UPCOMING/RECENT EVENT" section with a banner for "Latest 2022 Updates of the Indian Chemical Management and Safety Rules (CMSR)" and an "Online Event" link.

Thank You!

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IDEON Science Park, Beta 5.
Scheelevägen 17,
223 63 Lund, Sweden



compliance@gpcregulatory.com



+ 46 (0) 46 211 46 15



www.gpcgateway.com



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