ACTIONABLE SUMMARY
INDIAN CMSR

WHAT IS CMSR?

India released the fifth draft of the Chemical (Management and Safety) Rules (CMSR) on Aug. 24th, 2020. The CMSR will regulate Substances, Substances in Mixture, Substance in Articles and Intermediates that are manufactured, imported, or placed in the Indian Territory. The legal basis of the CMSR is section 3, 6, and 25 of the Environmental Protection Act (1986); Further enactment of CMSR will result in suspension of two existing rules - Manufacture, Storage and Import of Hazardous Chemical Rules (1989) and Chemical Accidents (Emergency Planning, Preparedness and Response) Rules (1996). The CMSR is expected to come into force in the early part of 2021. Indian manufacturers, importers and authorized representation (AR–acting on behalf of a foreign manufacturer) with an Indian legal entity can comply with the CMSR.

HOW TO COMPLY?

Notification

Notification is required for all substances that are in quantity above 1 TPA. Data Requirement for Notification: Submit Chemical information, Spectral data, Hazard Classification, Uses details, details of DU, Tonnage band, Storage capacity and SDS. A certificate of Notification along with Notification Number will be issued once the notified substance is evaluated for its completeness by the Chemical Regulatory Division. Annual reporting is required for all Notified substances, to be submitted on 29th Feb. / 1st Mar. each year, and any change in tonnage band or other notified information will be required to be promptly updated and may attract tonnage band change fee. All New Chemical Substances have to be notified at least 60 days prior to the date they are placed in Indian territory.

Registration

Only identified substances that are listed in "Priority Substances Required to be Registered" in Schedule II of the CMSR and with the tonnage exceeding 1 TPA need to be registered. Currently, there are 748 substances listed in Schedule II and the list would be updated. Registration should be carried out within 18 months after a substance is included in Schedule II. Technical dossiers should be submitted while registering substances. For substance with a tonnage band more than 10 TPA, a Chemical Safety Assessment is also required to be submitted along with Technical dossier. Registration fee will depend on tonnage band and company size. Joint submission is a recommended option. The Intermediates with the tonnage band less than 1000 TPA should be registered with only the physical and chemical properties in the Technical Dossiers. Whereas Intermediates with a tonnage band above 1000 TPA should register with full information in the Technical Dossier along with the Chemical Safety Report (CSR). Priority Substances in Article with the tonnage that exceeding 1 TPA will also need to register.

Annual Reporting

An annual report applies to all notified and registered substances. The report should contain the quantity of substance placed in Indian Territory in the previous calendar year and changes of information submitted at the time of notification. This should be done before the 29th Feb. / 1st Mar. of each calendar year.

FOREIGN MANUFACTURER AND AUTHORIZED REPRESENTATIVE

All Foreign Manufacturers/suppliers of substance, substance in mixture and priority substance in article should appoint an Authorized Representative (AR) with an Indian legal entity to comply with the CMSR compliance requirements. AR is a legal provision within CMSR made available only for Foreign Manufacturers/suppliers to comply with CMSR requirements.

GPC
Global Product Compliance

Key Terms

Existing Substance: refers to substances that are notified within the Initial Notification Period.

New Substance: refers to substances that are not notified within the Initial Notification Period.

Downstream User: is defined as any person within Indian Territory other than the Manufacturer and importer using the substance placed in the Indian Market for professional activity or industrial use. End use consumer is not accounted as a Downstream user.

Priority substances include the following:

1. Any Substance which falls under Hazard Classifications of the 8th revision of the United Nations Globally Harmonized System (GHS) of Classification and Labelling of Chemicals:
    a. Carcinogenicity and/or Germ Cell Mutagenicity and/or Reproductive Toxicity and categorised as Category 1 or 2, or
    b. Specific Target Organ Toxicity (Repeated Exposure or Single Exposure) Category 1 or 2; or
2. Any Substance which fulfils the criteria of Persistent, Bio-accumulative and Toxic or very Persistent or very Bio-accumulative, as set out in Schedule I; or
3. Any Substance listed in Schedule II;

Priority Substances in Article with a tonnage exceeding 1 tonne per year will also need to be registered. Schedule VI will be updated from time to time based upon the evaluation of notified substances.

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

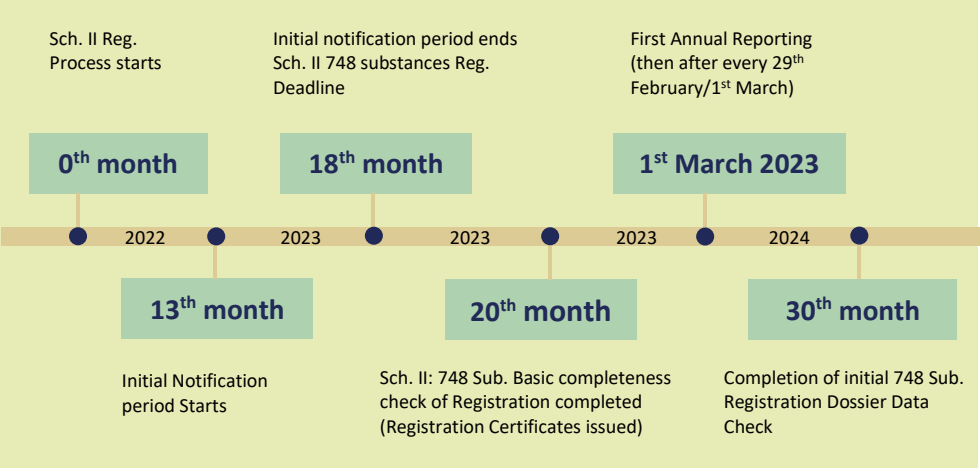
compliance@gpcregulatory.com

gpcgateway.com

linkedin.com/company/global-product-compliance-gpc-group/

ACTIONABLE SUMMARY
INDIAN CMSR

TIMELINE OF CMSR



Notification Data Requirement

- Notifier's Details
- Substance identifiers
- Impurities
- Substance structural details & Spectra
- Hazard Classification
- Uses
- Downstream Users
- Tonnage
- Max storage capacities
- SDS

Table 1: Timeline of CMSR implementation
Note: this table is prepared based on the assumption that Indian CMSR comes into force sometime in the early 2021

ACTIONS FOR MANUFACTURERS, IMPORTERS AND DU

- 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
- Internal training on the CMSR
- Follow up on the substance list (Substances to be registered (Schedule VI), Priority substances (Schedule II) and Hazardous substances (Schedule X, XI, XII)) with us on http://gpcgateway.com

Regulatory process	All substances	Substances to be registered	Priority substances	Hazardous substances
Listed in	Register of notified substances	Schedule VI	Schedule II	Schedule X, XI and XII
Process of Inclusion in Schedule	8(11)	8(12) & 8(13)	Unclear	16(3)
Definition/Criteria	2(1)(rr)	Unclear	2(1)(hh)	2(1)(i)
Notification (Rule 8)	Yes	Yes	Yes	Yes
Registration Requirements	No	Yes	Yes*	Yes*
Technical Dossier required	No	Yes	Yes*	Yes*
CSR / ES required	No	Yes*	Yes	Yes
SDS (UNGHS 16 Points)	Yes	Yes	Yes*	Yes*
Evaluation & Restriction	No	Yes*	Yes	Yes
Packaging & Labeling requirements	No	No	Yes	Yes
Import notification (authority)	No	No	Yes	Yes
Storage capacity Threshold	No	No	No	Yes
Compliance Status	Notification certificate	Registration certificate	Registration certificate*	Registration certificate*
Safety Audit	No	No	No	Yes
Site Safety Report	No	No	No	Yes
Emergency Preparedness	No	No	No	Yes

Table 2: Checklist for compliance requirement based on substance categories
*Further compliance required in the revised draft