Product Stewardship - INDIA REGULATION - (to be updated)

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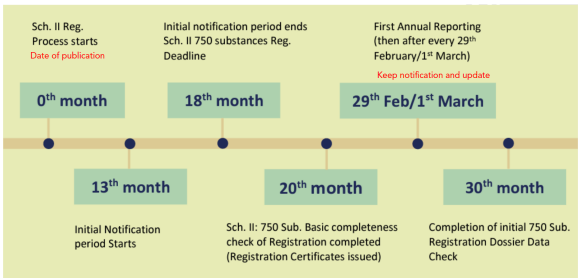
RECENT TRAINING MATERIAL

Welcome to Incredible INDIA

ICMSR: India's Chemicals (Management And Safety) Rules. (DRAFT)

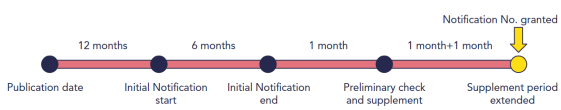
- **CMSR: Chemical Management and Safety Rules**
- **Released fifth draft of CMSR Aug 24th, 2020 (Here)**
- **Indian manufacturers, importers, and authorized representatives (AR - acting on behalf of a foreign manufacturer) with an Indian legal entity can comply with the CMSR.**
- **These Rules shall come into force on the date of publication**

Timeline of ICMSR (DRAFT)



Key Requirement (DRAFT)

- **Initial Notification**
    - **Scope: All substances introduced in India > 1T/yr**
- **Notification (After the expiry of Initial Notification Period)**
    - **Scope: > 1T/yr All NEW substances and Existing substances**
    - **All NEW substances >= 1T/yr and Existing substances > 1T/yr must be notified at least 60 days prior to import after Initial notification period termination**
    - **Notification No. shall be granted to the notifier**

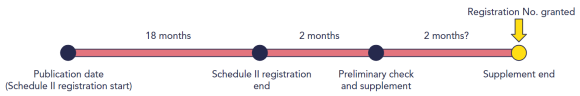


Data required	Notifier's details, Substances identifiers, Impurities, Substance structural details and Spectral data, Hazardous classification, Uses details, Details of Downstream users, Tonnage band, Storage capacity, SDS

- **Registration**
  - **Scope:**
    - **Intended to be released under normal or foreseeable conditions of use**
    - **Schedule II listed Substance: Here > 1T/yr**
    - **Schedule II substances in Articles > 1T/yr**
  - **Registration Due date: 18 months after included in Schedule II (from publication date)**
  - **Required data: Registration No. shall be granted to registrant**

Category	Tonnage band	Requirement
Substance	1-10 TPA	Technical dossier (Schedule VII)
	> 10 TPA	TD and Chemical safety report (Schedule VIII)
Intermediate	=< 1000 TPA	Physical/Chemical properties of TD
	> 1000 TPA	TD and CSR

  - **Content of Technical dossier: (Here) Robust summaries and Exposure scenarios included**
    - **Existing test data must be considered prior to requiring new test**
    - **New Tests must be approved by the Division for a test proposal and strategy**
    - **New Tests must be carried out in GLP/NABL certified labs and shall comply OECD TG**



- **Annual report (update notification information annually)**
  - **Scope: All notified substances**
  - **Required data:**
    - **Quantity of substance in the previous calendar year**
    - **Changes to the information submitted at the time of notification**
  - **Due date: before 29th Feb. / 1st Mar. of each calendar year**

Q: When can we expect implementation of the ICMSR?

- While the drafting process of the ICMSR is well advanced, some industry concerns have been put forward on the basis of the current draft. Additionally, a process of ministerial vetting must take place to ensure the proper fit of ICMSR with existing regulations.

- Once a final draft is produced, it must be submitted to the WTO and officially adopted by the Central Government (including a Gazette Notification).

- Another key period is the establishment of the Indian National Chemicals Authority (INCA), which is the leading authority in implementing ICMSR. While the Rules do not contain a clear timeline for this, it will involve the setting up of the Authority, the setting up of the system for Notification and Registration, and the issuance of relevant guidance.

INDIA BIS LICENCE

BUREAU OF INDIAN STANDARD (BIS)

BIS as the national standards body of India is committed promoting quality, safety, and innovation across various sectors through the development and implementation of standards and conformity assessment schemes.

Since the year 2000, the Bureau of Indian Standards (BIS) has been administering the Foreign Manufacturers Certification Scheme (FMCS) under the BIS Act of 2016 and the Rules & Regulations framed thereafter.

Under FMCS, BIS grants licenses to Foreign Manufacturers allowing them to use the Standard Mark on products that conform to Indian Standards. This scheme is applicable for products listed under mandatory certification across various product categories.

The licensing process is overseen by the Foreign Manufacturers Certification Department (FMCD) situated at BIS Headquarters in New Delhi.

Quality Control Orders

Quality Control Orders (QCOs) are formulated to safeguard consumer interests, promote fair trade practices, and maintain product quality and safety.

These are regulatory measures established to ensure that certain products meet specified quality standards before they are sold or distributed in the Indian market.

BIS, along with other regulatory authorities, enforces compliance with QCOs through inspections, testing, and monitoring activities. Non-compliance with QCOs may result in penalties, product recalls, or other regulatory actions.

BIS Certification Requirements (ISI Mark)

Manufacturers of regulated products must obtain BIS certification to demonstrate compliance with QCOs. Certification ensures that products undergo rigorous testing and assessment before entering the market. Scheme I under BIS conformity regulation 2018 provides the provision of Grant of Licence (GoL) to use ISI mark.

Critical Requirements for Foreign Manufacturers (per license)

Nomination of Authorized Indian Representative (AIR)

- **Requirement:** Mandatory
- **Purpose**: Appoint an Indian resident to handle BIS licence processes.

Manufacturing Site Inspection

- **Duration**: 2 days per factory
- **Conducted by:** BIS official
- **Purpose:** Verify plant layout, machinery, testing equipment, and product testing & sampling.

BIS Licence Manufacturing Premises

- **Requirement:** Must include premises where actual manufacturing and related activities occur.
- **Note:** ISI mark can only be applied by a licensed unit.

Testing at In-House Lab

- **Requirement:** Test methods & in-house equipment must comply with applicable Indian Standards.
- **Exception:** Some tests may be subcontracted.

Labelling/Marking

- **Requirement:** Must adhere to Indian Standards, including ISI mark & license number.

Online Consignment Portal

- **Responsibility:** Licensee must enter details of each ISI-marked consignment before entering India.

BIS Agreement & Indemnity Bond

- **Signed by:** AIR on behalf of the licensee.
- **When:** Within 15 days of Grant of Licence.

Performance Bank Guarantee (PBG)

- **Amount:** USD 10 000
- **Requirement:** Submit to BIS within 45 days after Grant of Licence.
- **Bank:** From any bank with an RBI-approved branch in India.

The standard timeline for GoL is 180 days but may vary for reasons such as delays in response to queries raised (if any),organizing inspection(s), transportation of samples and remittance of dues etc. Also due to revision of Indian Standard, VISA process timeline, country travel advisory, BIS inspector allotment & acceptance delays may occur.

The initial validity of licence is initially for a period of not less than one year and up to two years.

Check your products under mandatory certification!

Fee Structure

- **Phases:** Paid in 3 phases until Grant of Licence.
- **Currency:** Pay in USD directly to BIS.
- **Components:** Includes fixed and variable fees.

*** Annual Marking Fee**

- **Requirement:** For the ISI mark usage and calculated using total volume exported to India multiplied by per tonne rate assigned to each product IS.

Useful links

Recent drafts and Authority sites	Training materials	APA Engineering Market Regulation summaries
• **ICMSR draft** • **Gazette of India** • **ChemIndia** • **Indian Chemical Regulation Helpdesk**	• **INDIA REACH** • **ChemIndia Submission** • **Delve into BIS Certification for India Compulsory Registration Scheme (CRS)** • **Navigating chemical compliance in India**	

More questions? Join India RegWatch NW or Contact the Global Registration team.