



ASIA

REGULATORY BRIEFING

India

Chemical Regulatory Framework — Compliance Reference

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India

1 Chemical Inventory

In 2024, India launched **ChemIndia, a national chemical reporting and data platform** developed by the Department of Chemicals and Petrochemicals (DCPC) under the Ministry of Chemicals and Fertilizers [80]. The platform consolidates information on a wide range of chemicals and petrochemicals, including organic and inorganic substances, alkali chemicals, dyes and pigments, pesticides, polymers, synthetic fibres, elastomers, detergent intermediates, olefins, and aromatics.

Registered manufacturers and importers are required to submit detailed monthly data, including CAS number, IUPAC name, HS code, production volumes, and key mixture components, by the 10th of each month. Research and development chemicals are currently exempt, with reporting limited to commercial substances.

Formalized through the Gazette of India notification dated February 27, 2024, ChemIndia is mandatory and overseen by the DCPC under the Collection of Statistics Act, 2008. The data support the compilation of the Index of Industrial Production (IIP) and the annual publication Chemical and Petrochemical Statistics at a Glance. ChemIndia also provides policymakers and industry with a robust, real-time database and is expected to serve as the technical foundation for the future National Chemical Inventory under the forthcoming Indian Chemical (Management and Safety) Rules (ICMSR).

Under the forthcoming **Indian Chemical (Management and Safety) Rules (ICMSR)**, the competent authority will establish the National Chemical Inventory through a notification process [81].

Companies involved in the manufacture, import, or handling chemicals will be required to submit detailed information including company details, substance identifiers, impurities, tonnage, structural data and spectra, hazard classification, uses, downstream users, and maximum storage capacity to the Inventory.

The notification window will open one year after the ICMSR enters into force and will remain available for 180 days. Chemical substances that are notified during this period will be included in the National Chemical Inventory and be regarded as existing chemicals. The inventory is expected to be published following the closure of the notification period.

2 Status of GHS

India has not yet officially adopted the **Globally Harmonized System for Classification and Labelling of Chemicals (GHS)**. However, under the draft Chemical (Management and Safety) Rules (ICMSR) introduced in 2020, India plans to adopt the eighth revised edition of the GHS, including the standard 16-section Safety Data Sheets (SDS) format [81]. The languages for SDSs would be English and Hindi.

At present, SDS requirements are set out in Schedule 9 of the Manufacture, Storage, and Import of Hazardous Chemical Rules 1989. These provisions require only 9 of the 16 standard SDS sections.

Separately in 2011, India's Ministry of Environment and Forests (MoEF) introduced the draft **Hazardous Substances (Classification, Packaging and Labelling) Rules [82]**. The rules set out the responsibilities and procedures for stakeholders handling hazardous substances. These are defined as "any substance or preparation, which by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, or other living creatures, plants, micro-organisms, property or the environment". The legislation classified hazardous substances into categories such as explosives, gases, flammable liquids, flammable solids, oxidizing substances, toxic and infectious substances, radioactive materials, corrosive substances, and miscellaneous dangerous substances. These rules entered into force in 2013.

2.1 GHS in Transportation

In India, the transport of dangerous goods is regulated by the **Explosive Rules, 2008 [83]** and the **Central Motor Vehicle Rules, 1989 [84]**. The Explosive Rules (2008) incorporate recommendations from the **UN Committee on Transportation of Dangerous Goods** relating to explosives.

Under the Central Motor Vehicle Rules, 1989, provisions cover the educational qualification of drivers transporting dangerous or hazardous goods, the responsibilities of drivers and vehicle owners, requirements for emergency information panel, reporting obligations and the use of appropriate class labels.

3 Chemical regulation

India's current chemical management framework is based on older rules addressing hazardous chemicals, supplemented by certification requirements for specific substances. A new, more comprehensive system is expected once the **Indian Chemical (Management and Safety) Rules (ICMSR)** come into force.

3.1 Current Chemical Regulations

Two major sets of rules currently govern chemical management in India: The **Manufacture, Storage, and Import of Hazardous Chemicals Rules (1989)** [85] and the **Chemical Accidents (Emergency Planning, Preparedness, and Response) Rules (1996)** [86].

The Manufacture, Storage and Import of Hazardous Chemicals Rules regulate safety reporting for industrial installations handling hazardous chemicals, require producers to prepare emergency plans for chemical accidents, and set information requirements and control systems for the import of hazardous chemicals.

The Chemicals Accidents (Emergency Planning, Preparedness, and Response) Rules provide the legal basis for creating a system of Crisis Groups to prepare for and respond to chemical accidents. They also establish a Crisis Alert System to improve communication between authorities and the public.

In addition, a number of chemicals are regulated under the Bureau of Indian Standards (BIS) certification schemes. BIS, established under the **Bureau of Indian Standards Act 2016**, is the National Standards Body of India. The Act gives the government the authority to bring any goods, processes, system or service under compulsory certification when it considers this necessary in the public interest, for the protection of human, animal or plant health, for environmental or national security reasons, or to prevent unfair trade practices. There are two main product certification schemes: **Scheme 1** - Indian Standards Institution (ISI) and **Scheme 2** - Compulsory Registration Scheme (CRS).

60 chemicals have been added to the BIS list through Quality Control Orders (QCOs) with specific implementation timelines [87]. Manufacturers and importers of chemical substances on the BIS list must obtain certification before starting business activities. Non-Indian manufacturers can appoint an **Authorized Indian Representative (AIR)** to meet BIS certification requirements.

3.2 Chemical (Management and Safety) Rules

The existing regulatory framework in India does not fully address the challenges of modern chemical management. For instance, it lacks provisions for regulating substances that are carcinogenic, mutagenic, bio-accumulative, or toxic for reproduction. To close these gaps, the Indian government introduced the draft **Indian Chemical (Management and Safety) Rules (ICMSR)** in 2020 [81].

Once in force, the ICMSR will establish a procedure for substance notification, registration and restriction of substances, along with labeling and packaging requirements. It will also regulate safety procedures for the manufacture, handling, and import of chemicals, while providing the legal framework for managing chemical accidents.

The two existing sets of rules mentioned earlier will form the basis for Chapter IV of the ICMSR and will be repealed once the ICMSR comes into force.

3.3 Authority

According to the draft ICMSR, a chemical authority called the Indian National Chemical Authority (INCA) will be established. Under the INCA, a Steering Committee consisting of 16 government officials will be formed. This committee will nominate both the Risk Assessment Committee and the Scientific Committee and will also oversee the Chemical Regulatory Division, which will be further divided into nine units.

3.4 Substance Categories

3.4.1 Priority Substances

Under the current draft of the ICMSR, Priority Substances are identified through three main pathways.

First, substances that are classified for carcinogenicity, germ cell mutagenicity, or reproductive toxicity are considered Priority Substances, in line with the criteria for Categories 1 and 2 in the eighth revised edition of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS 8).

Second, substances that are persistent, bioaccumulative and toxic (PBT), as well as those that are very persistent and very bioaccumulative (vPvB), are also designated as Priority Substances. These groups are defined in Schedule I of the ICMSR, which sets thresholds for persistence, bioaccumulation, and toxicity.

Finally, all substances listed in Schedule II of the ICMSR are automatically considered Priority Substances. Schedule II of the current draft of the ICMSR includes 750 substances.

3.4.2 Restricted or Prohibited Substances

Restricted and Prohibited Substances will be listed in Schedule VI. The Indian National Chemical Authority (INCA) will evaluate substance registrations to determine whether a substance poses unacceptable risks to human health or the environment. Based on this assessment, substances may be restricted or prohibited.

At present, Schedule VI contains a single restricted substance, phosgene. Restricted substances may be used provided an authorization is obtained. Authorizations are granted for up to four years and may be renewed once. Criteria for granting authorizations include whether the substance is essential for industrial processes or for scientific research and development.

3.4.3 Hazardous Chemicals

The ICMSR defines hazardous chemicals using two approaches. First, Schedules X, XI, and XII list substances classified as Hazardous Chemicals. Second, any substance meeting the criteria in Part 1 of Schedule X is also considered hazardous. These criteria cover the toxicity, flammability, and explosiveness of chemicals.

3.5 Other Chemical-Related Obligations

The manufacture and import of chemicals in India are also regulated by the **Bureau of Indian Standards (BIS)**. BIS was established through an Act of Parliament dated November 26, 1986, and came into existence on April 1, 1987, with a broadened scope and more powers. It took over the staff, assets, liabilities and functions of the Indian Standards Institution (ISI).

Currently, BIS is a statutory body established under the Bureau of Indian Standards Act, 2016 which replaced the BIS Act, 1986. It was established for the harmonious development of standardization activities, and for the marking and certification of goods.

While BIS certification is generally voluntary, the Central Government may mandate compliance with Indian Standards for selected products when considered necessary in public interest, to protect human, animal, or plant health, for environmental or national security reasons, or to prevent unfair trade practices.

Such mandatory requirements are introduced through **Quality Control Orders (QCOs)**, under which manufacturers and importers must obtain a **License or Certificate of Conformity (CoC)** from BIS before starting business activities in India. Products for which QCOs have been issued are listed under **Scheme I** of the BIS product certification scheme.

60 chemical substances have been brought under compulsory certification through QCOs, each with specific implementation timelines [87]. There are few more chemical substances to come under mandatory certification in the near future.

3.6 Concerned Bodies

Compliance obligations under the ICMSR will vary according to the company's role in the supply chain, including Indian manufacturers, Indian importers, **Authorized Representatives (AR)**, and downstream users.

Manufacturers must comply with requirements for notification and registration, safety and emergency planning, as well as labeling and packaging. Importers are responsible for notification and registration, ensuring safe import of hazardous chemicals, and complying with labeling and packing requirements.

Under the ICMSR, foreign entities placing substances on the Indian market will have the possibility to appoint an AR, an Indian national or entity registered in India, to fulfil their compliance obligations.

4 Compliance Procedure

The draft ICMSR sets out stepwise procedures for notifying, registering, and managing chemical substances in India [81]. These provisions define when notification is required, what information must be submitted, and how substances will be classified as existing or new.

4.1 Notification

Notification will be required for all substances manufactured or imported a quantity above 1 tonne per annum (TPA). The timeline for notification is shown in Figure 8. Substances that are registered within the initial notification period will be classified as existing substances, while those not notified will be treated as new substances. New substances must be notified at least 60 days before being placed on the Indian market.

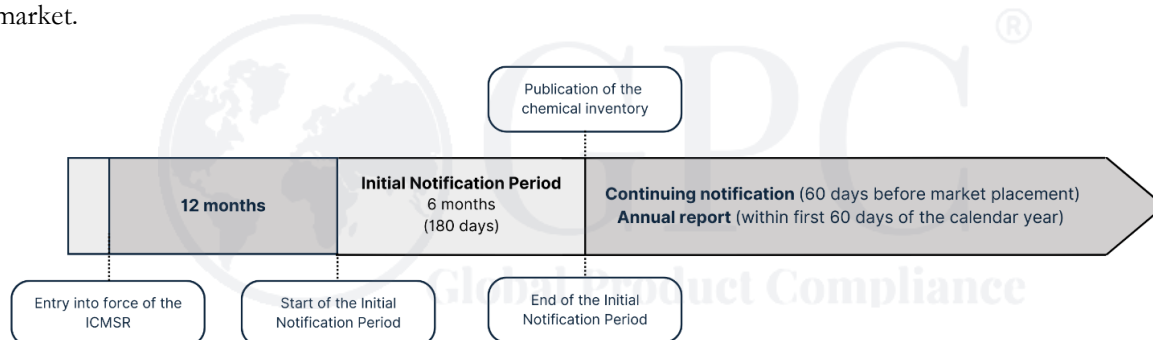


Figure 8 Notification timeline

For notification, applicants must submit the following information:

- Notifier details
- Substance identifiers
- Impurities
- Tonnage
- Structural details and spectra
- Hazard classification uses
- Downstream users
- Maximum storage capacity

4.2 Registration

Under the draft ICMSR, manufacturers and importers must register substances classified as Priority Substances. The current draft lists 750 substances in Schedule II that need to be registered. The schedule will be updated regularly. Registrants are also required to submit annual reports after initial registration. The registration timeline is shown in Figure 9.

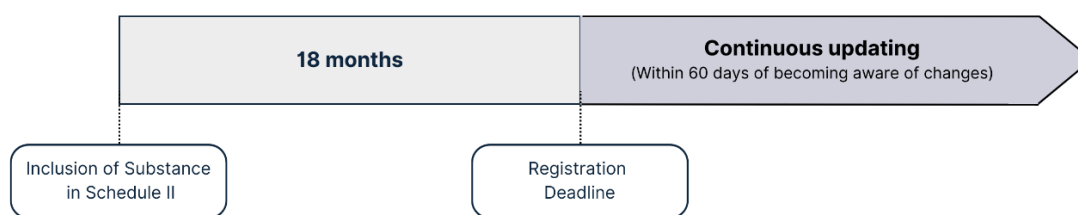


Figure 9 Registration timeline

For substances in Schedule II placed on the Indian market in quantities above 1 TPA, a Technical Dossier and an Exposure Scenario must be submitted. If the quantity exceeds 10 TPA, a Chemical Safety Report must be submitted instead of the Exposure Scenario (see Table 20).

Table 20 Registration requirements

Situation	Tonnage bands and obligations
Substances listed in Schedule II	Over 1 TPA: Technical Dossier and Exposure Scenario
Articles containing Schedule II Substances	
Intermediates that are Schedule II Substances	Over 10 TPA: Technical Dossier and Chemical Safety Report

Obligations for transported intermediates depend on the tonnages. When transported in quantities up to 1000 TPA, only the physical and chemical properties must be included in the Technical Dossier. For quantities above 1000 TPA, a full Technical Dossier and a Chemical Safety Report must be submitted. A registration fee will apply, based on the tonnage band and company size.

Under the current draft, the ICMSR does not regulate substances in articles except in two cases. First, if the article contains substances listed in Schedule II that are intended to, or likely to, be released under normal or foreseeable conditions of use, registration is required if the total quantity reaches 1 TPA. Second, if Schedule II substances are present in articles at concentrations above 1% weight by weight, manufacturers or importers must maintain an updated Safety Data Sheet (SDS) for the article, regardless of the overall tonnage of the substance.

4.3 Fees

Fees for notification and registration under the draft ICMSR are based on both the tonnage band and the size of the company. The applicable fees for notification and registration are provided in Tables 21 and 22, while the criteria for categorizing enterprises as micro, small, or medium (MSMEs) are listed in Table 23. To qualify for a category, enterprises must meet the thresholds for both investment and turnover.

Table 21 Notification Fee in Rupees and US Dollars

Tonnage band (TPA)	MSME		Large	
	INR	USD	INR	USD
1-10	10,000	113	25,000	284
10-100	30,000	341	75,000	852
100-1000	80,000	909	200,000	2,273
>1000	250,000	2840	600,000	6,818

Note: Exchange rates as of September 2025.

Table 22 Registration Fee in Rupees and US Dollars

Tonnage band (TAP)	MSME		Large	
	INR	USD	INR	USD
1-10	15,000	170	37,000	420
10-100	45,000	511	112,000	1,272
100-1000	120,000	1,363	300,000	3,410
> 1000	375,000	4,261	900,000	10,227

Note: Exchange rates as of September 2025.

Table 23 Criteria for MSME

Category	Investment in Plant/Machinery/Equipment		Turnover	
	INR	USD	INR	USD
Micro	10,000,000	113,650	50,000,000	568,225
Small	100,000,000	1,136,450	500,000,000	5,682,250
Medium	500,000,000	5,682,265	2,500,000,000	28,406,850

Note: Exchange rates as of September 2025.

4.4 Penalty for Non-Compliance

According to Article 35 of the draft ICMSR, companies violating the rules will face financial penalties. Violations include:

- Failing to notify or register a substance or intermediate within the given time frame.
- Providing false information during notification or registration.
- Purchasing an unregistered or unnotified substance.
- Failing to provide correct labeling or packaging of a Priority Substance.

Fines are set at INR 25,000 (approximately USD 300) per day for substances in the 1-1000 TPA tonnage band and INR 50,000 (approximately USD 600) per day for substances above 1000 TPA.

4.5 Annual Report

Under the draft ICMSR, applicants must submit an Annual Report for notified substances if any information/data provided during the initial notification has changed or requires updating. The report must also include the actual quantities of substances placed in the Indian market during the previous calendar year.