



Online Conference Chemical Regulatory Updates in India

**Latest Update on India's Draft Chemical Regulation**

Indian Draft Chemicals (Management & Safety) Rules 20XX (ICMSR)



Mr. Shisher Kumra,  
Executive Director  
Global Product Compliance (GPC)

Email: [shisher@gpcregulatory.com](mailto:shisher@gpcregulatory.com)

1



**Introduction to Draft ICMS Rules**

- Legal basis, Scope, Organization, obligation to notify. Notification

2

## GPC's Engagement in CMSR



**2010**

Ministry of Commerce / Chemexcil engaged SSS for Report

- Regulatory Status of EU REACH regulation and its Impact
- on Indian Industry Proposed Road-map for Indian Chemical Regulation



**2011-2018**

SSS was actively engaged with Ministry of Commerce and Dept. of Chemicals & Petrochemicals on the development of Draft National Chemical Policy



**JULY 2018**

SSS as a member of CII's National Chemicals Committee was engaged in drafting a proposal for chemical rules and - submitted it to the government



**JAN 2019**

SSS was asked to present the proposed draft Chemicals Rules in National Standard's Conclave organised by CII and Ministry of Commerce



**MAY 2019**

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



**2020**

Since mid 2019 the draft is being updated and has been circulated for comments by the industry bodies, with a latest 4th draft in March 2020 and a possible update expected after the stakeholder consultation meeting on 11th May 2020.

3

3

## Implementing Organizations

Indian National Chemical Authority (INCA) has 3 key organs

- Steering Committee (16 Govt. officials)
- Scientific Committee (10 members + 5 co-opt members)
- Risk Assessment Committee (8 members and 4 co-opt members)

### Chemical Regulatory Division

Chemistry Unit  
 Toxicology Unit  
 Chemical Accident Unit  
 Packaging & Labeling Unit

Techno-legal Unit  
 Priority Substance Unit  
 Information Technology Unit  
 Socio-Economic Unit

4

4

# ICMSR

- Chapter I – Definition, Objectives & Scope
- Chapter II – 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

## Authorized Representative

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

Foreign Manufacturer of

Substance	Substance in Mixture	Priority Substance in Article
-----------	----------------------	-------------------------------

Shall appoint an Indian Legal entity to comply with ICMS Rules on its behalf

# All substances if not exempted: Notify

- Any operator complying with other regulations – may also notify
- Polymers are substances
- Require to be notified within **Initial Notification Period** – 180 days
- Any operator – that has not notified in Initial Notification Period
  - New substance or Existing substance
  - 60 day prior to placing would submit Notification
- Notification is no free
- Annual Report – within 60 days (29<sup>th</sup> Feb. / 1<sup>st</sup> Mar each year)
- Indian Inventory – Register of Notified Substances
- Notification check & complication → Certificate of Notification



7

7

## Notification Data Required

- Notifier Details
- Substance Identifiers
- Impurities
- Substance Structural details & Spectra
- Hazard Classification
- Uses
- Downstream users
- Tonnage
- Max storage capacity
- SDS

**Schedule V - Information to be provided for Notification**

- Details of Notifier:
  - Name, address, phone, email of the Notifier
  - Name, address, phone, email of the person authorised to submit Notification
  - Details of foreign manufacturer, if the Notifier is an Importer or Authorised Representative
  - Location of the production and own use site(s), as appropriate
- 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.
- List all impurities with more than 1.0% but less than 10% (w/w) concentration
- For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), give the following details:
  - Structural representation of the constituents
  - Reaction scheme (including the identity of the reactants and the reaction type)
  - Process output (including identity of the precursors, the technology (method of preparation, process terms) and the typical composition)
- Chemical Structural Details
  - Molecular wt.
  - Simplified Molecular Input Line Entry System (SMILES)
  - Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
  - Spectral data:
    - High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
    - Infra Red spectra
    - Ultra Violet-Vis Spectrophotometer – spectra
    - Nuclear Magnetic Resonance
- Hazard Classification of the Substance (according to eighth revision of UN-GHS)
- Chemical uses
- Name of known Downstream Users (at least top 3; will be kept confidential)
- Actual quantity per annum in TPA (will be kept confidential under all circumstances)
- 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: 5<sup>th</sup> draft of ICMS Rules

8

8

# Notification Fee

Tonnage band of Substance	MSME	Large
1 – 10 TPA	10,000 ₹ (~140 \$)	25,000 ₹ (~350 \$)
10 – 100 TPA	30,000 ₹ (~420 \$)	75,000 ₹ (~1050 \$)
100 – 1000 TPA	80,000 ₹ (~1120 \$)	2,00,000 ₹ (~2800 \$)
> 1000 TPA	2,50,000 ₹ (~3500 \$)	6,00,000 ₹ (~8400 \$)

# Notification Certificate

## Part A- Notification Certificate

Notification Certificate	
issued under Rule 8 of the Chemicals (Management & Safety Rules), 20xx	
Name of the Notifier:	
Name of the Substance:	
Chemical Composition of Substance:	
Tonnage Band that the Substance falls under:	
Notification Number:	
Notification Date:	
Comments:	
Issued by	
Head, Chemical Regulatory Division	
Petroleum and Explosives Safety Organisation	

# Intermediates

- All Transported Isolated Intermediates (TII) needs to be Notified
- Intermediates that are Priority Substances to Be Registered:
  - < 1000 TPA – basic registration
  - > 1000 TPA – full registration



11

11

# Substance in Article

- Intended Release
- > 1 TPA
- Substance listed in Schedule II – Priority Substances to be Registered
- Has Only Registration and SDS Obligations
- No other obligations within the Rules are applicable



12

12

## Downstream Users (DU)

- Procure Notified or Registered substances as applicable
- Verify uses if included by the supplier
- Share uses with supplier to ensure its inclusion
- Confidential Uses / Uses Not included → DU to Notify
- DU to submit SDS for such uses – to Division
- May opt to register Schedule II Substance



13

13

A photograph of laboratory glassware including a large Erlenmeyer flask, a smaller Erlenmeyer flask, and a test tube, all containing a dark liquid. The background is a plain, light-colored surface.

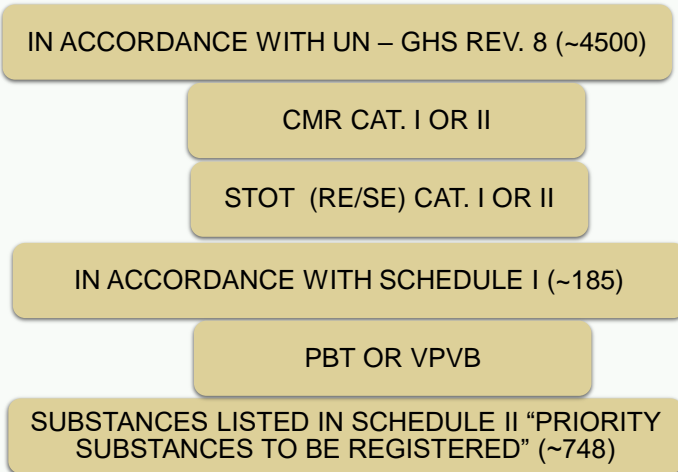
## Priority Substances

- Rule 2(hh) of Draft ICMS Rules

14

14






## Priority Substance



15

15

## Priority Substances

-  Potentially 4700 substances could be implicate based upon priority substance definition
-  labeling and packaging requirements (Rules 33 & 34)
-  Import of Priority substances requires to notify Authority 15 days before importation. (Rule 27)
-  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))

16

16



# 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 coincide 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  
submitting the  
registration,



Update Technical Dossiers -  
within 60 days of any  
change or revision in  
information



Technical  
Completeness of  
Dossier - within 60  
days



## Restricted and Hazardous Substances

- Schedule X, XI, XII of Draft ICMS Rules

## Restricted Substances:

- Registration data and CSR to be assessed to check for substances that may meet the criteria for:
  - Hazardous Substance
  - Restriction
  - Prohibition
- Restriction or Prohibited Substances Listed in Schedule IV
- Hazardous Substances be Listed in Schedule X, XI and XII
- Authorization for Restricted Substance is possible (4 + 4 years)
- Authorization Fee 1 M INR (14,000 \$)

19

19

## Specific Requirements: Hazardous Substances & Installations



Transport –Tracking & Communication System; Labeling,



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



Site Safety Report – Steps in accident prevention; Provide information, training, equipment and antidotes – for their safety



Isolated storage and quantity Thresholds (Schedule XI & XIII)



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.

20

20

# Fee Structure

## Registration Fee

Tonnage band of Substance	MSME	Large
1 – 10 TPA	15,000 ₹ (~210 \$)	37,000 ₹ (~518 \$)
10 – 100 TPA	45,000 ₹ (~630 \$)	1,12,000 ₹ (~2568 \$)
100 – 1000 TPA	1,20,000 ₹ (~1680 \$)	3,00,000 ₹ (~4200 \$)
> 1000 TPA	3,75,000 ₹ (~5250 \$)	9,00,000 ₹ (~12600 \$)

## Other Fee

Confidentiality claim	5,000 ₹ (~75 \$)	1,00,000 ₹ (~1400 \$)
Authorization	10,00,000 ₹ (~14000 \$)	10,00,000 ₹ (~14000 \$)
Filing an Appeal	10,000 ₹ (~140 \$)	1,00,000 ₹ (~1400 \$)

21

21



## Way Forward

- Preparedness for Businesses

22

22

# Summary

- Within first 18 Months: Notification (All) and Registration (748)
  - Follow-up on the substance lists –
    - Priority Substances (Rule 2(hh)) (~4200)
    - Substances to be Registered, (Schedule II) (> 748)
    - Hazardous Substances (Schedule X, XI, XII) (~700)
      - accordingly understand and prepare for upcoming requirements,
  - Technical Guidance & Templates to be made available
  - Dissemination Portal and e-filing
- “[GPCgateway.com](http://GPCgateway.com)” – remains a most updated source of info on the Rules and other regulations and is available for free to all uses.



23

23

## Substance Category & Regulatory Responsibility

Regulatory Process	All Substances	Priority Substances	Priority Substances to be Registered	Hazardous Substances
Definition / Criteria	2(1)(ss)	2(1)(hh)	2(1)(hh)	2(1)(l)
Listed in	Register of Notified substances		Schedule II	Schedule X, XI, XII
Process of Inclusion in Schedule	8(11)	8(12) & 8 (13)	8(12) & 8 (13)	16 (3)
Notification (Rule 8)	Yes	Yes	Yes	Yes
SDS (UNGHS 16 Point)	Yes	Yes	Yes	Yes
Compliance Status	Notification Certificate	Notification Certificate	Registration Certificate	Registration Certificate
Packaging & Labeling requirement	No	Yes	Yes	Yes
Import Notification (authority)	No	Yes	Yes	Yes
Registration Requirements	No	No	Yes	Yes
Technical Dossier required	No	No	Yes	Yes
CSR / ES required	NO	No	Yes	Yes
Evaluation & Restriction	No	No	Yes	Yes
Storage capacity Threshold	No	No	No	Yes
Safety Audit	No	NO	No	Yes
Site Safety Report	No	No	No	Yes
Emergency Preparedness	No	No	No	Yes

24

24



# Thank you.

CONTACT US FOR GLOBAL REGULATORY SERVICES



[Http://gpcgateway.com](http://gpcgateway.com)



[compliance@gpcregulatory.com](mailto:compliance@gpcregulatory.com)



[global-product-compliance-group](https://www.linkedin.com/company/global-product-compliance-group)



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

© Global Product Compliance (GPC) - Group