

Latest Update on India's Draft Chemical Regulation

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



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1

Today's agenda

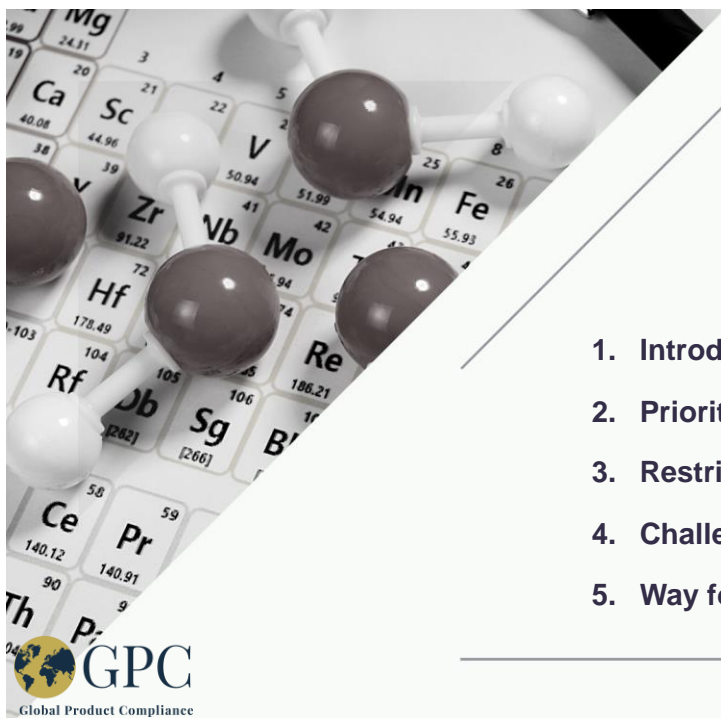
Introduction	Jess Hsu Regulatory Manager, GPC
Opening notes	Mr. Deepak Gupta Acting Executive Director , Chemexcil
Presentation	Mr. Shisher Kumra Executive Director, GPC
Q&A session	
Closing notes	Mr. Prafulla Walhe Deputy Director, Chemexcil



CHEMEXCIL

Basic Chemicals, Cosmetics & Dyes Export Promotion Council
(Set up by the Ministry of Commerce & Industry Government of India)

2



Summary of Topics

1. Introduction to Draft ICMSR Rules
2. Priority substances
3. Restricted and hazardous substances
4. Challenges with Current Draft
5. Way forward for Companies

2010

- Ministry of Commerce / Chemexcil engaged GPC (then SSS) for a Report on the Regulatory Status of EU REACH and its impact on Indian Industry
- Proposed Road-map for Indian Chemical Regulation

2011-2018

- GPC (then SSS) was actively engaged in the development of the Draft National Chemical Policy

July 2018

- Within CII's National Chemicals Committee, GPC (then SSS) was engaged in drafting a proposal for chemical rules which was submitted to the government

May 2019

- CII and GPC (then SSS) were the only non-governmental representatives in a Ministry of Commerce's technical committee to review and adapt the proposed chemical rules, which were adopted as an official draft

Currently

- The draft has been circulated among industry bodies for comments
- After legal vetting and ministerial feedback, a possible update and submission are expected in 2022



Introduction to Draft ICMS Rules

Legal basis
Scope
Organization
Obligation to notify
Notification

5

5

Legal basis and objectives

- Based on Sections 3, 6 and 25 of the Environment (Protection) Act, 1986
- Objective: High level of protection to human health and the environment
- Will supersede:
 - Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
 - Chemical Accidents (Emergency, Planning, Preparedness and Response) Rules, 1996

6

6

Scope

- The Rules apply to:
 - Substances, Substances in Mixtures and Intermediates
 - Substances in Articles (partially)
 - Manufactured, Imported, Placed or intended to be Placed in Indian Territory
- Key definition: Substances

7

7

Scope – Substances (1/2)

A chemical element and its compounds, in their natural state or obtained by any manufacturing process.

- Including: any additive necessary to preserve its stability and any impurity derived from the process used
- Excluding: Solvents that may be separated without affecting the stability of the substance or changing its composition

Rule 2(ss) Draft ICMSR

8

8

Scope – Substances (2/2)

The term includes:

- Substances in Mixtures – Rule 2(m)
- Intermediates – Rule 2(x)
- Substances in Articles (more limited obligations)

Exempted substances, such as:

- Food and feeding stuff for human beings or animals
- Schedule IV Substances
- Wastes
- Substances for re-exporting

Rule 2(ss) Draft ICMSR

9

9

Implementing Organizations

Indian National Chemical Authority (INCA)

1. Steering Committee

- 16 Government officials

2. Scientific Committee

- 10 members + 5 co-opted members

3. Risk Assessment Committee

- 8 members and 4 co-opted members

Chemical Regulatory Division

- Chemistry Unit
- Toxicology Unit
- Chemical Safety and Accidents Unit
- Packaging and Labelling Unit
- Techno-legal Unit
- Priority Substance Unit
- Information Technology Unit
- Socio-Economic Unit

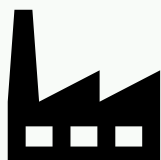
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10

ICMSR – Overall structure

- Chapter I – Definition, Objectives and 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
- Schedules (I to XIX)

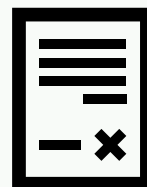
Who can notify/register substances?



**Indian
Manufacturers**



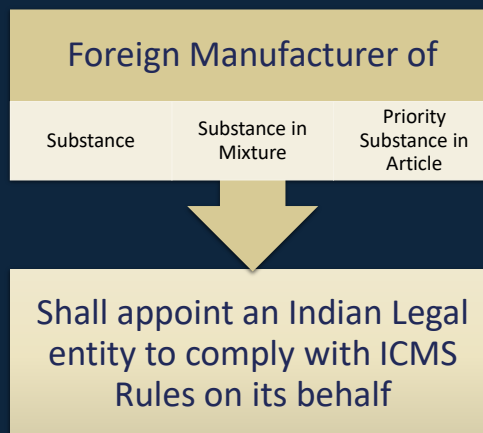
**Indian
Importers**



**Authorized Representative
(with legal entity in India)**

Authorized Representative

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



13

13

All substances if not exempted: Notify (1/2)

- 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
 - New substance or Existing substance
 - 60 day prior to placing would submit Notification

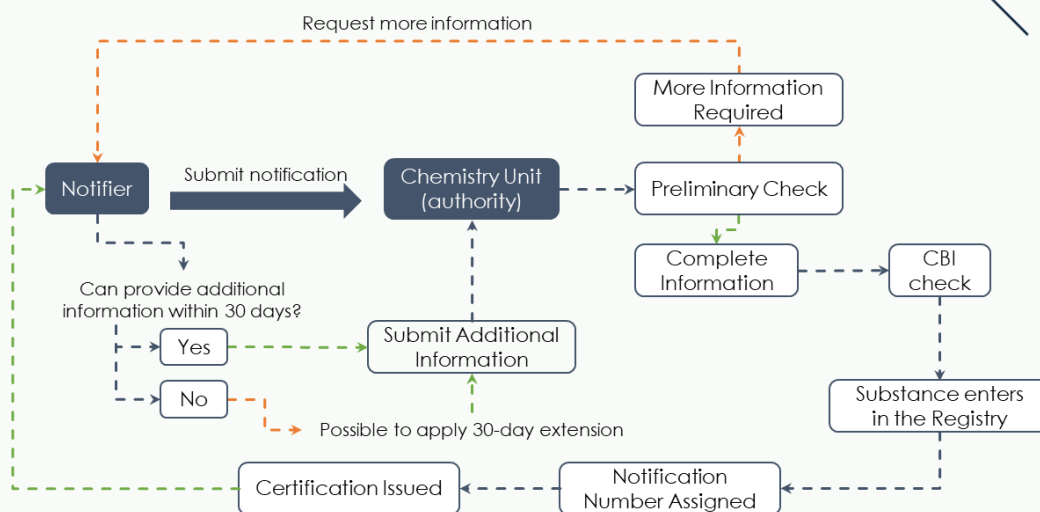
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14

All substances if not exempted: Notify (2/2)

- Notification is not free
- Annual Report – within 60 days (29th Feb. / 1st March each year)
- Indian Inventory – Register of Notified Substances
- Notification check & complication → Certificate of Notification

Notification Procedure



Data required 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

- 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: 5th draft of ICMS Rules

17

17

Notification Fees

Substance tonnage band	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 \$)

18

18

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	

19

19

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**

20

20

Downstream Users - Definition

Any natural or juristic person in India who uses a substance in the course of his industrial or professional activities

Excluded:

- Manufacturers
- Importers
- End-use consumers

Rule 2(h) Draft ICMSR

21

21

Downstream Users – Duties

- Procure substances that have been Notified or Registered as applicable
- For uses not included in a Substance's Notification:
 - Notify
 - Submit an SDS for such uses

Rule 7 Draft ICMSR

22

22

Downstream Users – Advice

- Verify uses included by the supplier in Notification/Registration
- Share uses with supplier to ensure their inclusion
- May opt to register if the substance is a Schedule II Substance

23

23



Priority Substances

Rule 2(hh) of Draft ICMSR

24

24

Priority substances

- In accordance with UN – GHS Rev. 8 (~4500):
 - CMR Cat. I or II
 - STOT (RE/SE) Cat. I or II
- PBT/vPvB in accordance with the criteria in Schedule I (~185)
- Substances Listed in Schedule II “Priority Substances to Be registered” (~748)

Priority substances



Potentially 4700 substances could be implicate based upon priority substance definition



Labelling 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))

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.

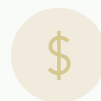
*Deadline coincides with
Initial Notification period*



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



Restricted and Hazardous Substances

Schedules X, XI and XII of Draft ICMSR

Restricted Substances (1/2):

- Registration data and Chemical Safety Reports to be assessed to check for substances that may meet the criteria for:
 - Hazardous Substance
 - Restriction
 - Prohibition

29

29







Restricted Substances (2/2):

- Restriction or Prohibited Substances Listed in Schedule VI
- 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 \$)

30

30

Specific Requirements: Hazardous Substances & Installations

-  Transport –Tracking & Communication System; Labeling,
-  Safety Audit of installation – within 6 month; every 2 years (Sch. XI & XII)
-  Site Safety Report – Steps in accident prevention; Provide information, training, equipment and antidotes – for safety employee / implicated. (Sch. X, XI, XII)
-  Isolated storage and quantity Thresholds (Schedule XI & XIII)
-  Onsite / off-site Emergence Preparedness Plan within 3 months; (on-site - mock drill every 6 month)
-  Notification of Accident within 24 hrs; report within 72 hrs.

31

31

Fee Structure

Registration Fee

Substance tonnage band	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 \$)

32

32



Issues with current draft

33

33

Suggested Changes for 6th Draft

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) in addition to the Schedule II substances.
4. Explicit mentioning of the SDS language in the regulation, priority wise English and the local language.

Substance Specific:

1. Clarification of Polymer Registration – multiple Mol. Wt. would have same CAS and the toxicity profile may vary. If its in Schedule II then we may need Registration. In EU, UK, Korea, Turkey - Monomers and additives of polymers are to be registered (Notified) instead of a Polymer.
2. Suggestion of lower data requirements for Intermediate (for > 1000 TPA) because of no exposure to general public.
3. Clarity on Nano-forms at a later date at least when registration is operational.

Logistical and Administrative:

1. Update on Scientific and Risk Assessment Committee members to avoid conflict of interest (E.g., from GLP labs).
2. 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.
3. Proposal on updating the non-compliance penalty from per day to within a period of 1-2 months.
4. Suggestion for notification of New-substances – 60 days prior to placing in the Indian Market.
5. Defining specific data requirements for the annual reporting template.

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34

34

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 Registered 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

35

35



Way Forward

Preparedness for Businesses

36

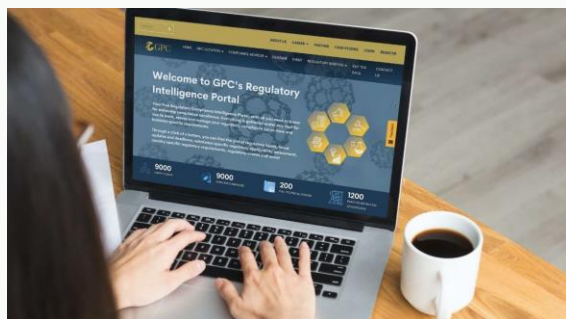
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Substance Category & Regulatory Responsibility

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

37

37



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38

38



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