

ICC

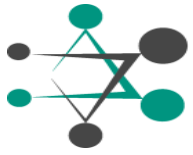


India Draft Chemicals (Management & Safety) Rules, 20xx

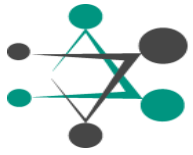
Dr Pranav Tripathi

Deputy Director - Sustainability, Environment, and Regulatory Issues

Indian Chemical Council



- Objective of India Draft Chemicals (Management & Safety) Rules, 20xx
- Content of the draft Rules
- Chapter II: National Chemical Authority
- Chapter III: Notification, Registration and Restriction on Use
- Intermediates
- Safety Data Sheet
- Labelling Requirement
- Exemption
- Timeline
- Summarize the ICMSR through flow diagram



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Objective of Draft Chemicals (Management & Safety) Rules, 20xx



What is Covered?

- Notification
- Registration
- Restrictions,
- Labelling and Packaging requirement

Health & Environment

- Safety Procedures for the Manufacture, Handling and Import of Hazardous Chemicals and preparedness and management of Chemical
- Accidents related to Hazardous Chemicals
- Protection to human health and the environment

Rules are Framed for

- All Substances
- Substances in Mixtures
- Intermediates that are Manufactured
- Imported, Placed or Intended to be Placed in Indian Territory
- *Substances in Articles (Conditional)*

Chapter (6)

Chapter I: Definitions, Objectives & Scope

Chapter II: National Chemical Authority

Chapter III: Notification, Registration, & Restrictions on Use

Chapter IV: Safety and Accident Preparedness

Chapter V: Labelling and Packaging

Chapter VI: Miscellaneous

Schedules (19)

Schedule I: PBT and vPvB Assessment Criteria

Schedule II: List of Priority Substances to be registered (750 substances)

Schedule III: Concerned Authorities

Schedule IV: Substances exempt from Chapter III (Notification, Registration & Restriction on Use) and Chapter V (Labelling and Packaging)

Schedule V: Information to be provided for Notification

Schedule VI: Restricted or Prohibited Substances

Schedule VII: Content of Technical Dossier

Schedule VIII: Format for Chemical Safety Report

Schedule IX: Safety Data Sheet

Schedule X: Hazardous Chemicals (669 Substances)

Schedule XI: Isolated storages at Installations other than covered by Schedule XIII

Schedule XII: List of Hazardous Chemicals for application of Chapter IV (Safety & Accident Preparedness (185 Substances or group of Substances)

Schedule XIII: Industrial installations

Schedule XIV: Information to be furnished by Occupier

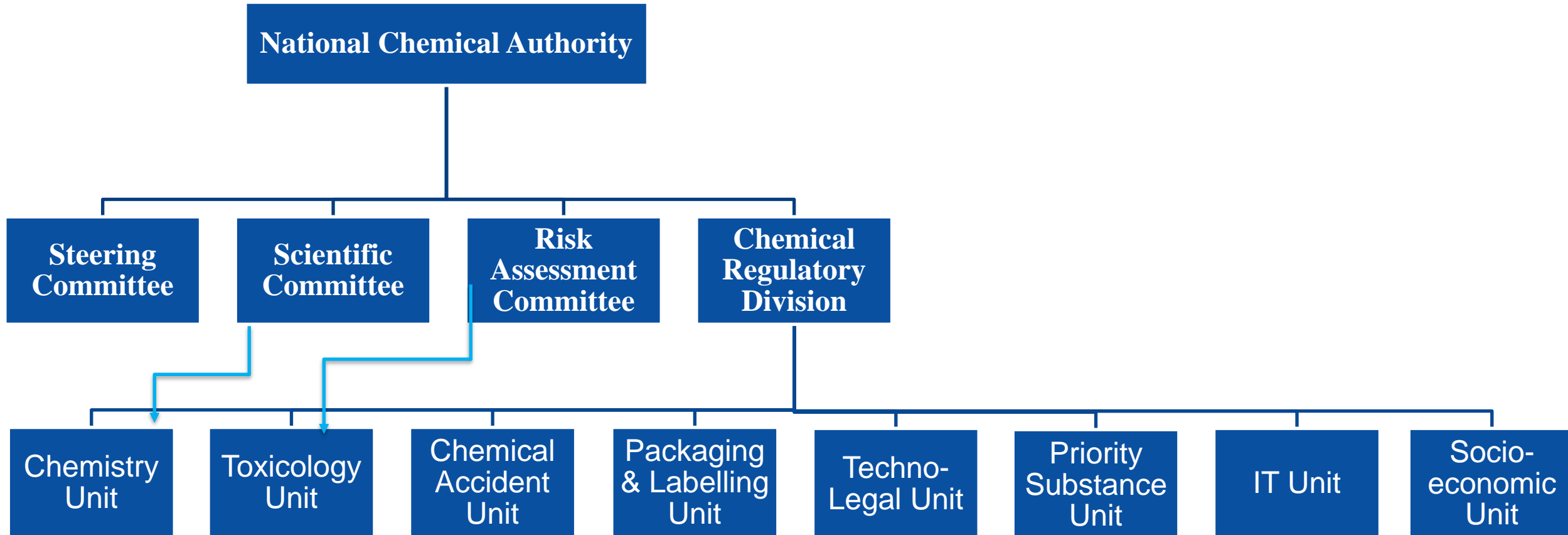
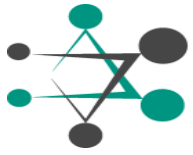
Schedule XV: Details to be furnished in the Offsite Emergency Plan

Schedule XVI: Information to be furnished regarding Notification of Chemical Accident

Schedule XVII: Information in Labelling

Schedule XVIII: Format of Certificate

Schedule XIX: Fees and Fines Payable



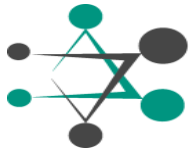
6. Placing in Indian Territory

A Foreign entity who wishes to Place a Substance, Mixture or Article in Indian Territory **may appoint an Authorised Representative**

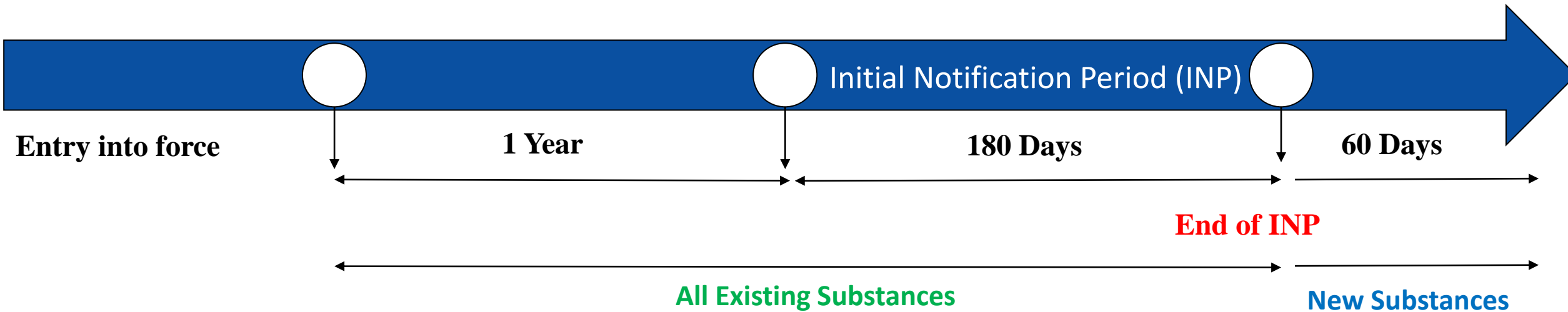
7. Duty of Downstream Users

(1) A **Downstream User** shall not procure Substances, Mixtures, Intermediates or Articles in which Substances or Intermediates have not been Notified or Registered, as applicable, in accordance with these Rules.

(2) Every Downstream User whose Use of a Notified Substance is not included in its Notification, shall notify the Division of such Use and submit a Safety Data Sheet in relation to such Use in accordance with Rule 12.



Notification Timeline



Notification (for New Substances)

✓ A Manufacturer or Importer or Authorized Representative shall Notify the Division of any New Substance that they intend to Place in Indian Territory, **after the expiry of the Initial Notification Period**, at **least 60 days prior** to the date on which they are Placed in Indian Territory in quantities more than 1 tonne per annum.

✓ Also for Existing Substance in quantities greater than 1 tonne per annum in Indian Territory after the INP, they shall be Notified to the Division in the same manner

Data Requirements for Notification

1. Detailed information of the Notifier
2. Substance identification information
3. Impurities
4. Unknown Substances Details
5. Substance structural information and spectra
6. Hazard classification
7. Usage
8. Downstream user
9. Tonnage
10. Maximum storage capacity

1. Details of Notifier:

- a. Name, address, phone, email of the Notifier
- b. Name, address, phone, email of the person authorised to submit Notification
- c. Details of foreign manufacturer, if the Notifier is an Importer or Authorised Representative
- d. Location of the production and own use site(s), as appropriate

2. 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. |
|-------|------------|-------------|---------|---------------------|--------|-------------|
| | | | | | | |

3. List all impurities with more than 1.0% but less than 10% (w/w) concentration

4. For substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB), give the following details:

- a. Structural representation of the constituents
- b. Reaction scheme (including the identity of the reactants and the reaction type)
- c. Process output (including identity of the precursors, the technology (method of preparation; process terms) and the typical composition)

5. Chemical Structural Details

- a. Molecular wt.
- b. Simplified Molecular Input Line Entry System (SMILES)
- c. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
- d. Spectral data:
 - i) High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
 - ii) Infra Red spectra
 - iii) Ultra Violet-Vis Spectrophotometer – spectra
 - iv) Nuclear Magnetic Resonance

6. Hazard Classification of the Substance (*according to eighth revision of UN-GHS*)

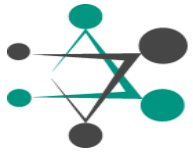
7. Chemical uses

8. Name of known Downstream Users (*at least top 3; will be kept confidential*)

9. Actual quantity per annum in TPA (*will be kept confidential under all circumstances*)

10. 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.)

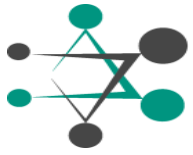


- Notification shall be deemed accepted
- Substance will be entered in the **Register of Notified Substances**
- A **Notification Number** will be issued to the Notifier for each substance
- A **Notification Certificate** shall be issued to the Notifier
- Priority Substance unit shall **check** if the substance **falls under the Priority Substance**

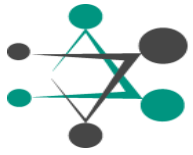
Schedule XVIII – Format of Certificates

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 |



- Substances listed in Schedule II **(750 Substances) in quantities >1 tonne per annum**; to be done within one and a half year of inclusion of substance in Schedule II
- Even for Substances in quantity less than 1 tonne per annum, Registration may be required on recommendation of Steering Committee and the Division
- In case of Substances in Articles, intended for release, if the quantity of substances set out in Schedule II, present in the Article exceeds 1 tonne per annum, it requires Registration
- Technical Dossier needs to be submitted as per Schedule VII for Registration



- Preliminary Check by Toxicology
- Deemed acceptance of the Registration
- Assigning of the Registration Number
- Issuance of Certificate of Registration
- Additional time of 60 days for incomplete applications
- **Data Submitted to other Regulators in other countries will be accepted** to the extent possible.
- **Joint Registration of a Substance is permitted**

Part B – Registration Certificate

Registration Certificate

issued under Rule 10 of the Chemicals (Management & Safety Rules), 20xx

Name of Registrant:

Name of the Substance:

Chemical Composition of Substance:

Tonnage Band that the Substance falls under:

Notification Number:

Registration Number:

Registration Date:

Comments:

Issued by Head, Chemical Regulatory Division

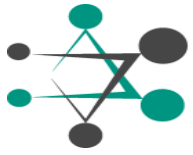
1. Registrant Detailed
2. Chemical identifiers
3. Chemical Structural Details
4. Identified Chemical Uses
5. Classification and Labelling Information
6. Robust Study Summaries
7. Main Use Categories
8. Specification for Industrial and professional use
9. Significant route(s) of exposure
10. Environmental Exposure
11. Pattern of exposure

Schedule VII - Contents of Technical Dossier

1. Registrant Details:
 - a) Name of Legal Entity
 - b) Name of Submitter
 - c) Legal Representative of the Registrant
 - d) Contact details – address; phone; email
 - e) Location of site of production or use
 - f) Company Registration Number, if applicable
 - g) GST Number, if applicable
 - h) Plant site code, if applicable
2. Chemical identifiers
 - a) Chemical Name: IUPAC Name or Common/Trade Name or CAS Name
 - b) Chemical Numbers: CAS Number and IN Number / Notification number
 - c) Purity
 - d) Details of all impurities contained in concentrations of greater than 0.1% (w/w)
 - e) Nature of impurities, including isomers and by-products
 - f) Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)
3. Chemical Structural Details
 - a) Molecular wt.
 - b) SMILES
 - c) Molecular and structural formula
 - d) Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
 - e) Spectral data:
 - i) High Performance Liquid Chromatography or Gas Chromatography or Gas Chromatography Mass Spectrometry or Liquid Chromatography Mass Spectrometry
 - ii) Infra Red spectra
 - iii) Ultra Violet-Vis Spectrophotometer – spectra
 - iv) Nuclear Magnetic Resonance
 - v) Mass spectrum
 - f) Type of substance – mono, multi, 'Unknown or Variable Composition, Complex Products or of Biological Methods'.
 - g) Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.
4. Identified Chemical uses
 - a) The calendar year of the registration
 - b) An indication of the tonnage used for his own use(s)
 - c) Form (substance, preparation or article) and/or physical state under which the substance is made available to downstream users.
 - d) Concentration or concentration range of the substance in preparations made available to downstream users and quantities of the substance in articles made available to downstream users.
 - e) Brief general description of the identified use(s)
 - f) Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses
 - g) description of the manufacturing process and
 - h) all identified uses that the Registrant wants to cover in accordance with use descriptors. (These uses shall be included in the Exposure Scenario (1 – 10 TPA) and Chemical Safety Report as the case may be.)
5. Classification and labelling information
 - a) The hazard classification of the substance(s),
 - b) The resulting hazard label for the substance(s)
 - c) Specific concentration limits, where applicable
6. Robust study summaries
7. Main use category:
 - a) industrial use and/or
 - b) professional use and/or
 - c) consumer use
8. Specification for industrial and professional use:
 - a) used in closed system and/or
 - b) use resulting in inclusion into or onto matrix and/or
 - c) non-dispersive use and/or
 - d) dispersive use
9. Significant route(s) of exposure:

Human exposure:

 - a) oral and/or
 - b) dermal and/or
 - c) inhalatory
10. Environmental exposure
 - a) water and/or
 - b) air and/or
 - c) solid waste and/or
 - d) soil
11. Pattern of exposure:
 - a) accidental/infrequent and/or
 - b) occasional and/or
 - c) continuous/frequent



Evaluation

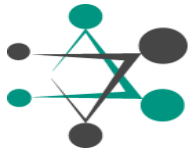
By Chemistry & Toxicology Unit within one year of its submission

Incomplete information

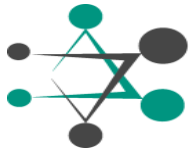
Within 120 days of being intimation

Further extension

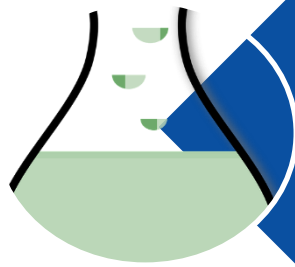
Maximum extension for 90 days



- All intermediates transported/stored within India: **Notification + Registration**
- *In situ* intermediates, consumed in the same process: **No Notification & Registration**
- All Intermediates, which are also Substances included in [Schedule II](#), and are stored in a facility (either for consumption in-situ or otherwise): **Registration**
- Transported Intermediates that are Substances included in [Schedule II](#), shall be Registered as under:
 - a. registration of Intermediates transported or to be transported in quantities **up to 1000 tonne per annum** shall only contain details regarding the **physical and chemical properties in the Technical Dossier**
 - b. registration of Intermediates transported or to be transported in quantities **greater than 1000 tonne per annum** shall contain all information as required in the **Technical Dossier and the Chemical Safety Report**
- Intermediates **not included in Schedule II**, are required **to be Notified**, but are **exempted from Registration**



Safety Data Sheet



All Substances or Intermediates listed in Schedule II or Hazardous chemicals Article, where a substance or intermediate listed in Schedule II is present in such Article >1.0% (w/w)



Downstream user shall recommend that their uses are included in the Safety Data Sheet



Updating of Safety Data Sheet- Whenever new information of hazard or anything that affect risk management becomes available

Schedule IX – Safety Data Sheet

The safety data sheet shall include the following 16 headings in the given sequence and in addition the subheadings are also listed; pictograms, hazard statements, warning and other relevant information are based upon the UN-GHS classification criteria.

Section 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

Section 2: Hazards identification

- 2.1. Classification of the substance or mixture
- 2.2. Label elements
- 2.3. Other hazards

Section 3: Composition/information on ingredients

- 3.1. Substances
- 3.2. Mixtures

Section 4: First aid measures

- 4.1. Description of first aid measures
- 4.2. Most important symptoms and effects, both acute and delayed
- 4.3. Indication of any immediate medical attention and special treatment needed

Section 5: Fire fighting measures

- 5.1. Extinguishing media
- 5.2. Special hazards arising from the substance or mixture
- 5.3. Advice for fire fighters

Section 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
- 6.2. Environmental precautions
- 6.3. Methods and material for containment and cleaning up
- 6.4. Reference to other sections

Section 7: Handling

- 7.1. Precautions for safe handling
- 7.2. Conditions for safe storage, including any incompatibilities
- 7.3. Specific end use(s)

Section 8: Exposure controls/personal protection

- 8.1. Control parameters
- 8.2. Exposure controls

Section 9: Physical and chemical properties

- 9.1. Information on basic physical and chemical properties
- 9.2. Other information

Section 10: Stability and reactivity

- 10.1. Reactivity
- 10.2. Chemical stability
- 10.3. Possibility of hazardous reactions

- 10.4. Conditions to avoid
- 10.5. Incompatible materials
- 10.6. Hazardous decomposition products

Section 11: Toxicological information

- 11.1. Information on toxicological effects

Section 12: Ecological information

- 12.1. Toxicity
- 12.2. Persistence and degradability
- 12.3. Bioaccumulative potential
- 12.4. Mobility in soil
- 12.5. Results of PBT and vPvB assessment
- 12.6. Other adverse effects
- 12.7 Other Information

Section 13: Disposal considerations

- 13.1. Waste treatment methods

Section 14: Transport information

- 14.1. UN number
- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- 14.5. Environmental hazards
- 14.6. Special precautions for user
- 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Section 15: Regulatory information

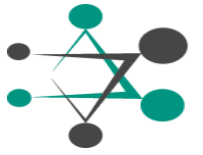
- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
- 15.2. Chemical safety assessment

Section 16: Legal Status of Substance

Information on legal status of the Substance in other jurisdictions, i.e. specifically information on whether the Substance has been restricted or prohibited under any other laws for the time being in force, or under any other jurisdiction.

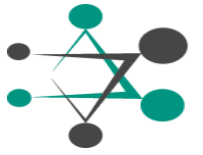
Section 17: Other information

Including information on preparation and revision of Safety Data Sheet, sources of information.



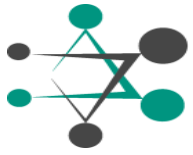
Labelling Requirement

- All priority substances, hazardous chemicals, or mixtures containing **>10% (w/w) of any Priority Substance, hazardous Chemicals to bear label as per Schedule XVII**
- All product identifiers, hazard statements and pictograms, signal words, and precautionary statements used in the label of Priority substances shall be in **accordance with UN GHS (ver. 8)**
- The label shall be in **English and Hindi**

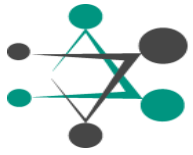


The following are exempted from the CMSR:

- **Radioactive** Substances.
- Substances **under customs supervision**, not being placed in Indian Territory.
- Substances **stored in customs free zones** with aim of re-exporting.
- **Wastes**, as defined in **Hazardous Waste Management Rules 2016**.
- Substances used for the **purposes of defense**.
- Substances **used as food** or feeding stuff for human beings or animals, including human or animal nutrition.



| Rules Enforced | 0th Month (When??) |
|--|--|
| Emergency Plan (Hazardous Substances) | 3 rd Month (Deadline) |
| Safety Audit (Hazardous Substances) | 6 th Month (Deadline) |
| Initial Notification Starts | 13 th Month (12 month after) |
| Initial Notification Closes | 18 th Month |
| Initially Listed: Registration | 18 th Month |
| New Substances Notification | 18 th Month onwards (90 days prior) |
| No New Substances to be Placed | 19 th to 21 st Month |
| Annual Report | 30 th Jan Each Year |
| 1 st Completeness: Registration | 21 st Month (within 90 days) |



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Stakeholders



Notifiers / Registrants

- Person Placing substance in Indian Territory
1. Manufacturer
 2. Importer
 3. Formulator
 4. Packer
 5. Seller
 6. Distributor

Down Stream User

Authorized Representative Of Foreign Manufacturer

National Chemical Authority

Chemical Regulatory Division

Secretariat

Steering Committee

Scientific Committee

Risk Assessment Committee

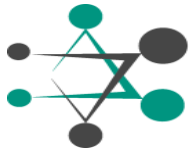
Enforcement / Concerned Authority (Schedule III) or Competent Authority

Units of the Division

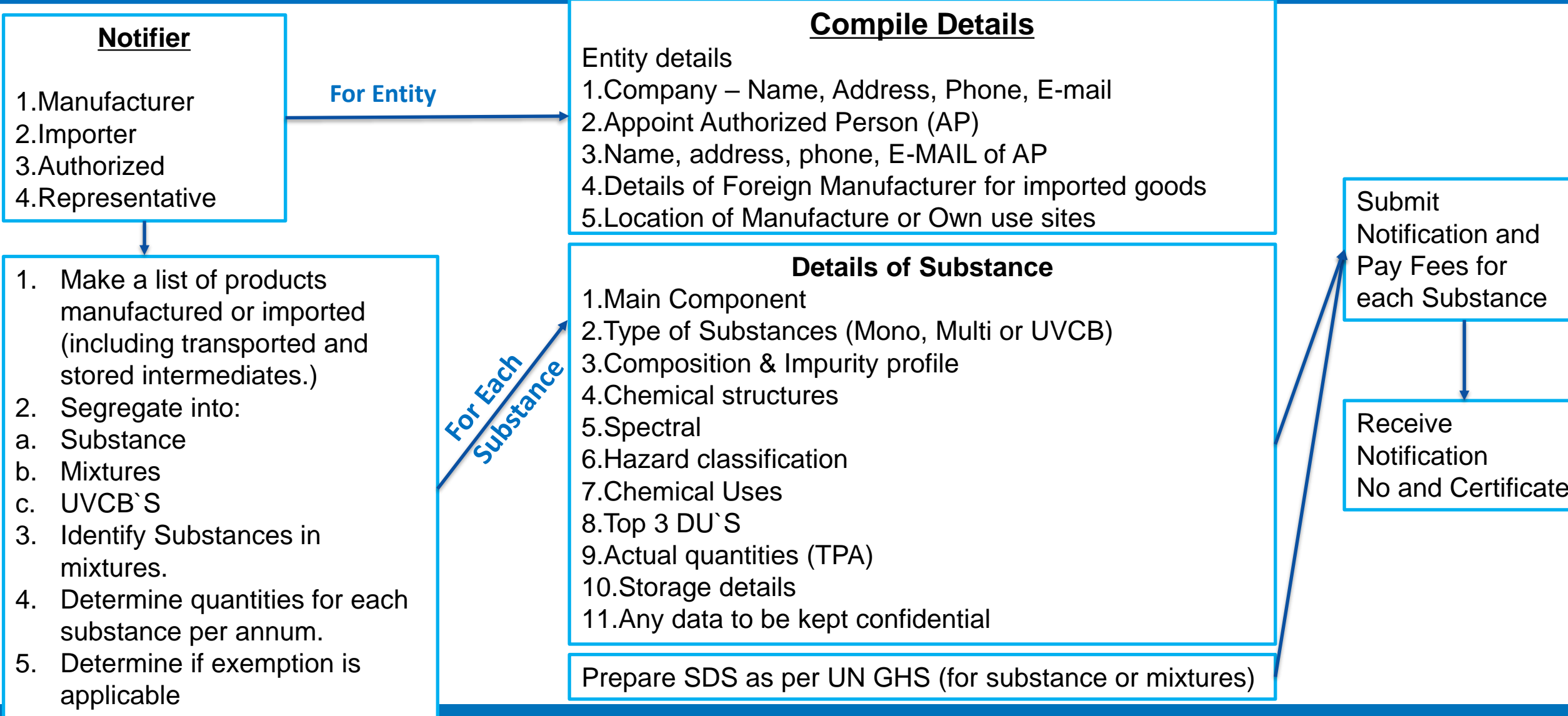
1. Chemistry Unit.
2. Toxicology
3. Chemical Safety and Accident unit
4. Packaging & Labelling Unit
5. Techno – Legal Unit
6. Priority Substance Unit
7. Information Technology Unit
8. Socio – Economic Unit

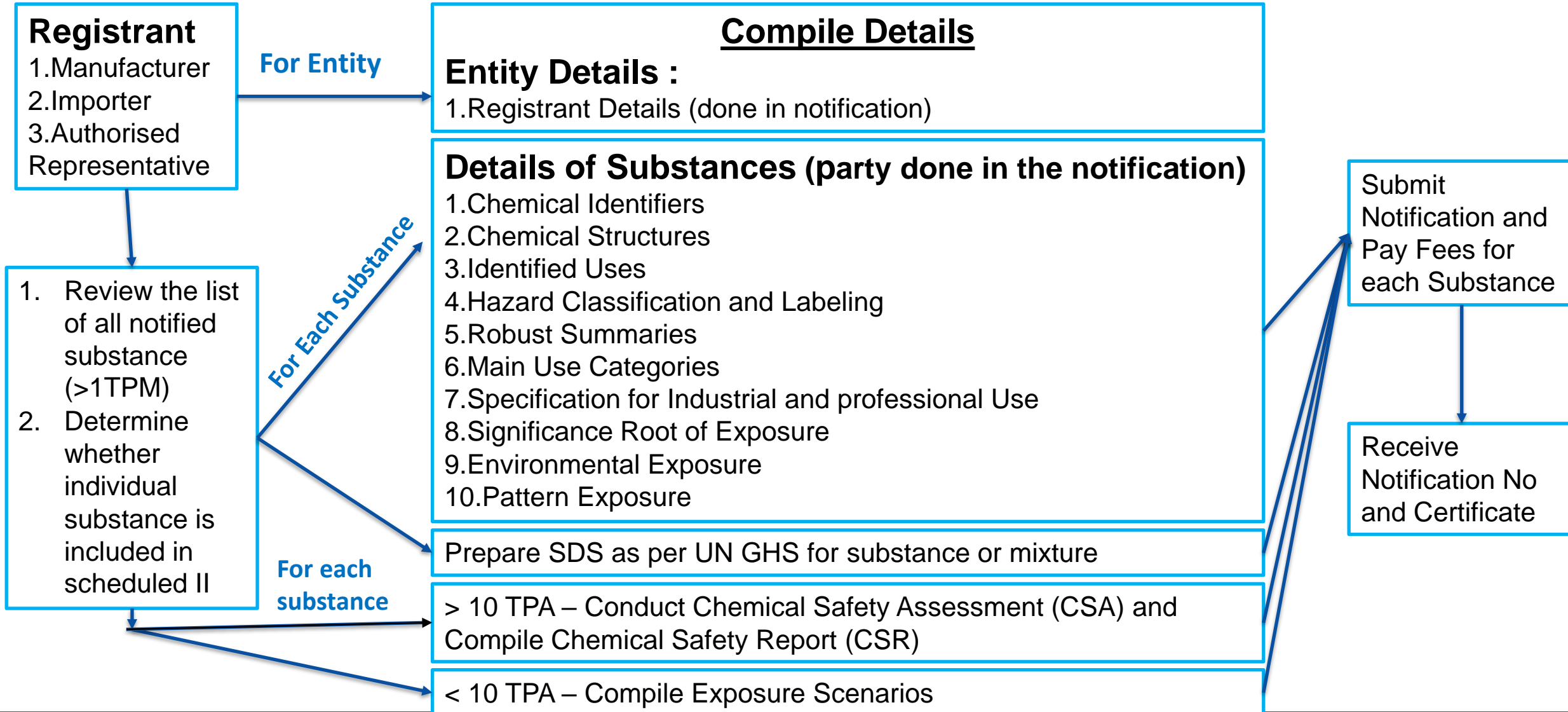
Public





Process flow for Notification







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