

Online Conference Chemical Regulatory
Updates in India

Notification, Annual Reporting and Registration Process within Draft Indian CMSR



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CMSR – Discussion on

- **Key Terminology with CMSR**
- **Schedules within in CMSR**
- **Timeline – notification & registration**
- **Roles & Obligation within CMSR**
- **Notification – Data required, process & evaluation**
- **Annual reporting process and requirements**
- **Registration - Data required, process & evaluation**
- **Intermediate Substance registration**
- **Chemical Safety Report and its requirement**
- **Technical dossier evaluation and restriction**
- **Testing and Appeals**



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CMSR - Key words

- **Substance** means 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 deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the Substance or changing its composition.
- **Substance; Substance in Mixture; Mixture; Articles;**
- **New Substance, Existing Substance;**
- **Priority Substance; Hazardous Substance;**
- **Chemical Accident; handling and Import of Hazardous Chemicals and preparedness and management of Chemical**
- **Industrial Activity; Occupier ; Manufacturer ; Importer**
- **CHAPTERS (6) & SCHEDULES (19)**
- **Notification, Registration and initial notification period**



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CMSR - Schedules

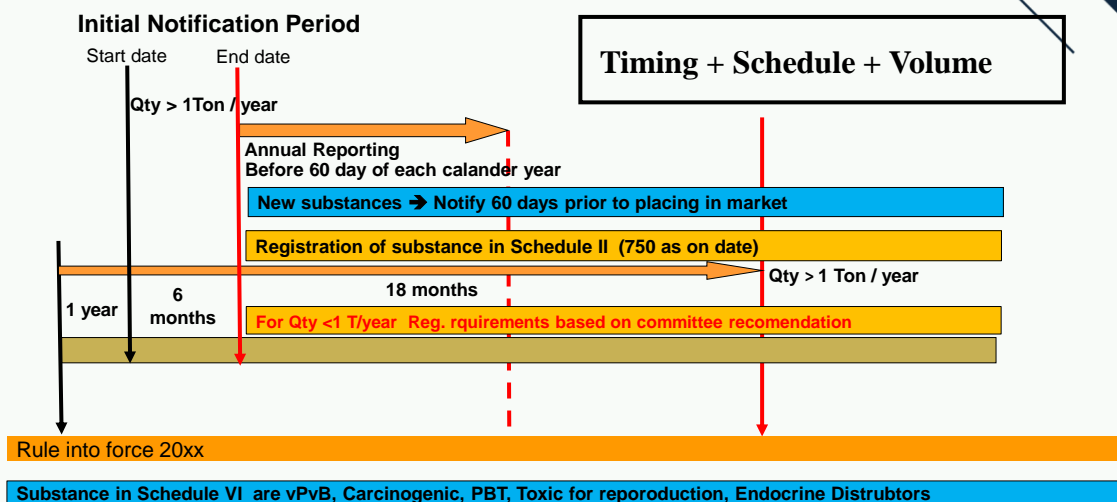
| Schedule | Title |
|----------|--|
| I | PBT & vPvB Assessment Criteria |
| II | List of Priority Substances (750 Subs. To be registered) |
| III | Concerned Authorities |
| IV | Substances Exempted for the purpose of Chapter III & V |
| V | Information to be provided for Notification |
| VI | Restricted or Prohibited Substances (01 as on date, will be added later...) |
| VII | Contents of Technical Dossier |
| VIII | Format for Chemical Safety Report |
| IX | Safety Data Sheet |
| X | Hazardous Chemicals (669 Substances, will be added latter....) |
| XI | Isolated Storage At Installations Other Than Those Covered By Schedule XIII (30 Subs.) |

| Schedule | Title |
|----------|--|
| XII | List of Hazardous Chemicals for Application of Chapter IV (Safety & Accident Preparedness) (179 Subs. + Flammable Gas & Liquids) |
| XIII | Industrial Installations (Alkylation, Condensation, Hydrolysis, Sulphonation & so on...) |
| XIV | Information to be Furnished by the Occupier |
| XV | Details to be Furnished in the Off Site Emergency Plan |
| XVI | Information to be Furnished Regarding Notification of a Chemical Accident |
| XVII | Information in Labelling |
| XVIII | Format Of Certificates |
| XIX | Fees and Fines Payable |



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Draft Summary Time Line



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CMSR - Roles & Obligations: Manufacturer, Importer & DU

- ❖ Notification of substances within the initial notification period
- ❖ New substance: Notify substance 90 days in advance of placing substance in market.
- ❖ Annual reporting of notified substances
- ❖ Information up and down supply chain
- ❖ Registration of substances in Schedule II
- ❖ SDS of priority substance or hazardous substance or intermediate to be as per GHS version 8.
- ❖ Safety Audit Report for substances exceeding threshold quantity of Schedule XI & XII
- ❖ Downstream user shall not procure Substance, Mixture, Intermediate or Articles in which substances or intermeidate have not been Notified or Registered as applicable.



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CMSR - Notification Data Requirement : Schedule V

| Sr. No. | Information to be provided for Notification | |
|---------|---|--|
| 1 | Name of Notifier | Details of the legal entity |
| | | Name of the submitter |
| | | Legal Representative of the Notifier if any |
| | | Contact details - address, phone, email |
| | | Details of foreign manufacturer, if the notifier is an importer or Authorized Representative |
| 2 | Chemical Identifiers | Chemical name IUPAC Name or Common name |
| | | Chemical number: CAS number and IN Number |
| | | Purity in percentage |
| | | Details of all impurities contained in concentration of greater than 0.1 (w/w) |



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CMSR - Notification Data Requirement : Schedule V

| Sr. No. | Information to be provided for Notification | |
|---------------|---|---|
| 3 | Chemical Structural Details | Molecular Weight |
| | | Simplified Molecular Inputs Line entry System (SMILES) |
| | | Molecular and structural formula |
| | | Information on optical activity and typical ratio of (Stereo) isomers (if applicable and appropriate) |
| | | Type of substance - Mono, multi, unknown or variable composition complex product or of biological method (UVCB) |
| | | Spectral Data |
| | | HPLC |
| | | GC |
| | | LCMS |
| | | Infra Red Spectra |
| | | Ultra Violet Vis Spectrophotometer - Spectra |
| | | Nuclear Magnetic Resonance (NMR) |
| Mass spectrum | | |



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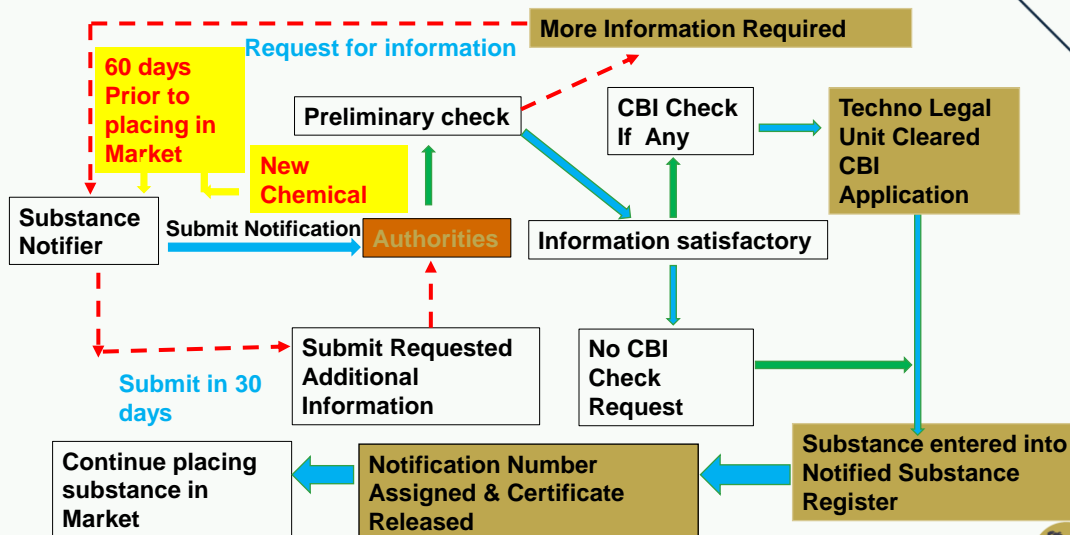
CMSR - Notification Data Requirement : Schedule V

| Sr. No. | Information to be provided for Notification |
|---------|--|
| 4 | Hazard Classification of the substance (GHS Rev. 8) |
| 5 | Chemical uses (Primary, secondary1, secondary 2....) |
| 6 | Name of known Downstream Users |
| 7 | Tonnage band (1-10, 10-100; 100-1000, > 1000 TPA) placed in Indian Territory |
| 8 | Actual Quantity per annum TPA (To be kept confidential) |
| 9 | Maximum storage capacity / maximum quantity stored |



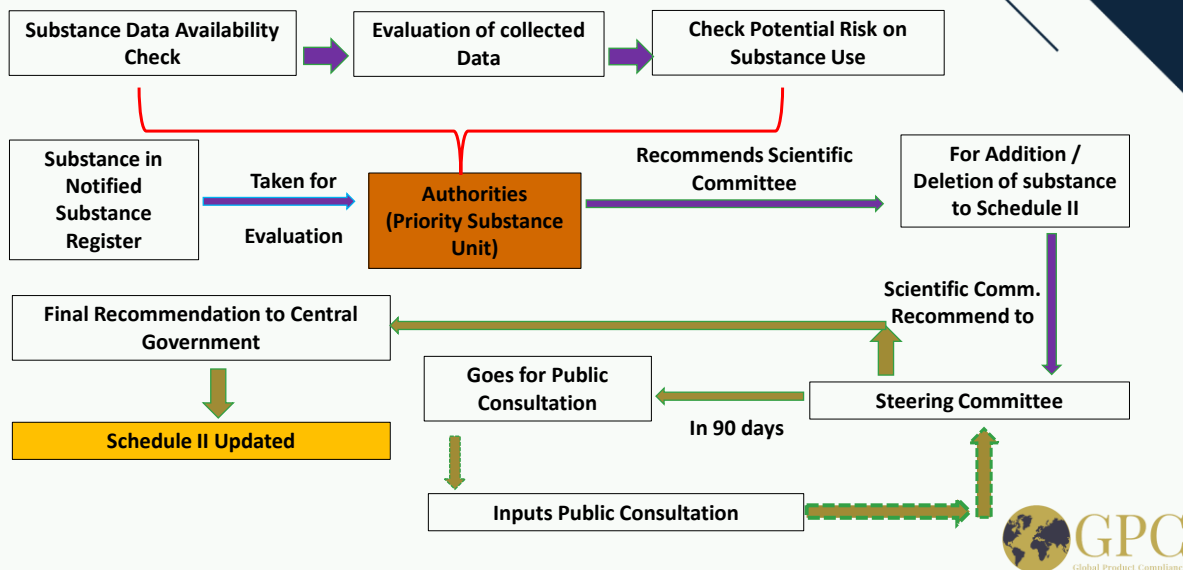
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CMSR - Notification Process:



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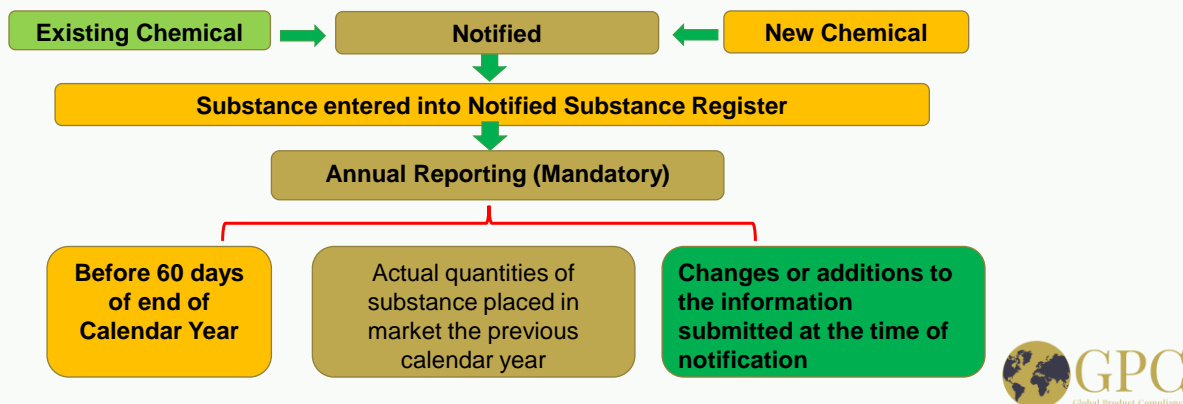
Post Notification – Evaluation Process



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CMSR - Annual Reporting of Substances

- Applicable to all notified Existing and New Substances
- **Report should contain:**
 - Actual quantities of substance placed in Indian Territory in the previous calendar year
 - Changes or additions to the information submitted at the time of notification



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CMSR – Substance Registration

Registration Mandatory for substances already placed or intend to be placed in market and as listed in Schedule II

Eligible for registration : Quantity Greater than 1 Ton/Year

For quantities Less than 1 Ton / Year : Requirement for such volume may be published in Schedule VI based on recommendation of Authorities

Substance in Article:

1. If they are intended or likely to be released from the Article under normal or foreseeable conditions of use and
2. Such substances is present in the Article in quantities totalling over 1 ton /year in the produce or the import

Substance added to Schedule II; Register within 18 months from date of its addition. !!!

Joint Registration is valid for the same substance !!!



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CMSR –Registration Data Requirement

| Sr. No. | Schedule VII - Contents of Technical Dossier | |
|---------|--|---|
| 1 | Registrant Details | Legal Entity Name |
| | | Name of Submitter |
| | | Legal Representative of the Registrant |
| | | Contact details – address; phone; email |
| | | Location of site of production or use |
| | | Company Registration Number, if applicable |
| | | GST Number, if applicable |
| | | Plant site code, if applicable |
| 2 | Chemical identifiers | Chemical Name; IUPAC Name; Common/Trade Name; CAS Name |
| | | Chemical Numbers – CAS Number; IN Number |
| | | Purity |
| | | Details of all impurities contained in concentration of greater than 0.1% (w/w) |
| | | Nature of impurities, including isomers and by-products |
| | | Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors) |



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CMSR – Substance Registration

| Sr. No. | Schedule VII - Contents of Technical Dossier | |
|---------|--|---|
| 3 | Chemical Structural Details | Molecular wt. |
| | | SMILES |
| | | Molecular and structural formula |
| | | Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate) |
| | | Spectral data: |
| | | i) HPLC or GC or GCMS or LCM |
| | | ii) Infra Red spectra |
| | | iii) UltraViolet-Vis Spectrophotometer – spectra |
| | | iv) Nuclear Magnetic Resonance |
| | | v) Mass spectrum |
| | | Type of substance – Mono, Multi, UVCB (Unknown or Variable Composition, Complex Products or of Biological Methods). |
| | | 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. |



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CMSR – Substance Registration

| Sr. No. | Schedule VII - Contents of Technical Dossier | |
|---------|--|---|
| 4 | Identified Chemical uses | The calendar year of the registration |
| | | An indication of the tonnage used for his own use(s) |
| | | Form (substance, preparation or article) and/or physical state |
| | | Concentration or concentration range of the substance and quantities of the substance in articles made available to downstream users. |
| | | Brief general description of the identified use(s) |
| | | Information on waste quantities and composition of waste resulting from manufacture of the substance , the use in articles and identified uses |
| | | Description of the manufacturing process and |
| | | All identified uses that the Registrant wants to cover in accordance with standardised use descriptors. (These uses shall be included in the Exposure Scenario (1 – 10 TPA) and Chemical Safety Report as the case may be.) |



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CMSR – Substance Registration

| Sr. No. | Schedule VII - Contents of Technical Dossier | |
|---------|---|---|
| 5 | Classification and labelling information | The hazard classification of the substance(s), |
| | | The resulting hazard label for the substance(s) |
| | | Specific concentration limits, where applicable |
| 6 | Robust study summaries | |
| 7 | Main use category | Industrial use and/or |
| | | Professional use and/or |
| | | Consumer use |
| 8 | Specification for industrial and professional use | Used in closed system and/or |
| | | Use resulting in inclusion into or onto matrix and/or |
| | | Non-dispersive use and/or |
| | | Dispersive use |



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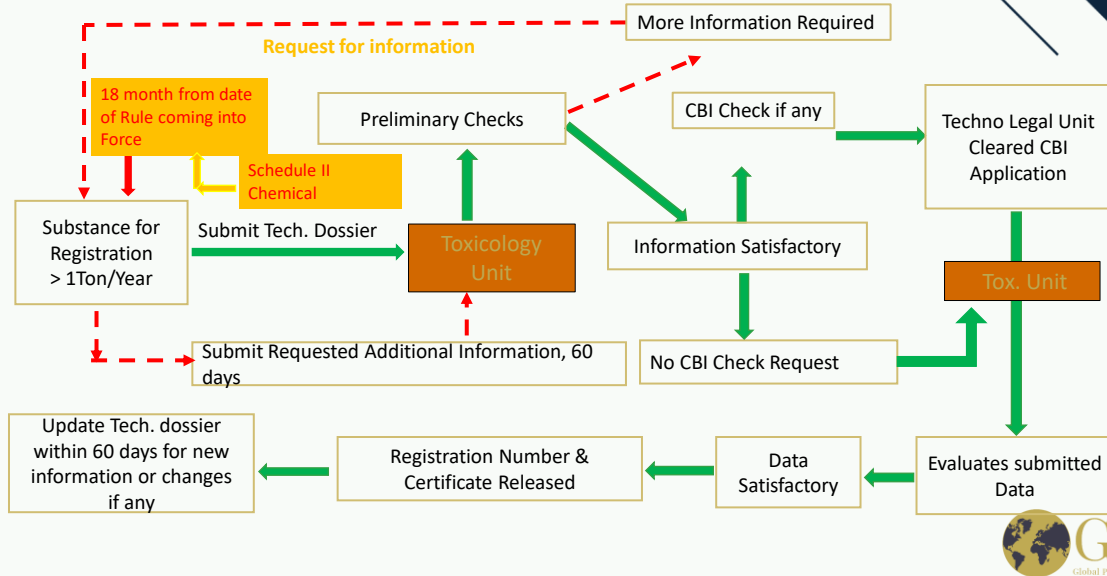
CMSR – Substance Registration

| Sr. No. | Schedule VII - Contents of Technical Dossier | |
|---------|--|------------------------------|
| 9 | Significant route(s) of exposure | Human exposure: |
| | | Oral and/or |
| | | Dermal and/or |
| | | Inhalatory |
| 10 | Environmental exposure | Water and/or |
| | | Air and/or |
| | | Solid waste and/or |
| | | Soil |
| 11 | Pattern of exposure: | Accidental/infrequent and/or |
| | | Occasional and/or |
| | | Continuous/frequent |



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CMSR– Registration Process



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CMSR – Intermediate Substance Registration

- ❑ Intermediates substances (To be Transformed into Another Substance upon Use) those are transported, stored or will be transported and stored shall comply with the Rules
 - ❑ Intermediates produced in-situ which are not isolated but consumed in the same process are exempted from Notification and Registration.
 - ❑ All Intermediates, which are also Substances included in Schedule II, and are stored in a facility (either for consumption *in-situ* or otherwise) shall be Registered in accordance with Rule 10 of these Rules.
- ❑ **Transported** Intermediates substance included in Schedule II shall be registered as under:
1. Registration upto 1000 Ton / year shall only contain details of physical and chemical properties in Technical Dossier.
 2. Registration greater than 1000 Ton / year shall contain all information as required in the Technical Dossier and in addition a Chemical Safety Report will be required.

Intermediate substance not included in Schedule II are exempted from Registration :

But to be Notified !!!

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CMSR – Chemical Safety Assessment

☐ For Substances included in Priority Substance List & placed in market :

- Volume > 10 Ton / Year: Perform Chemical Safety Assessment
 - Submit a Chemical Safety Report during Notification or Registration
- If Volumes are < 10 Tons /Year
 - Submit an Exposure Scenario at the time of Notification or Registration.

Submit CSR for Volume > 10 Ton / Year during Notification & Registration !!!



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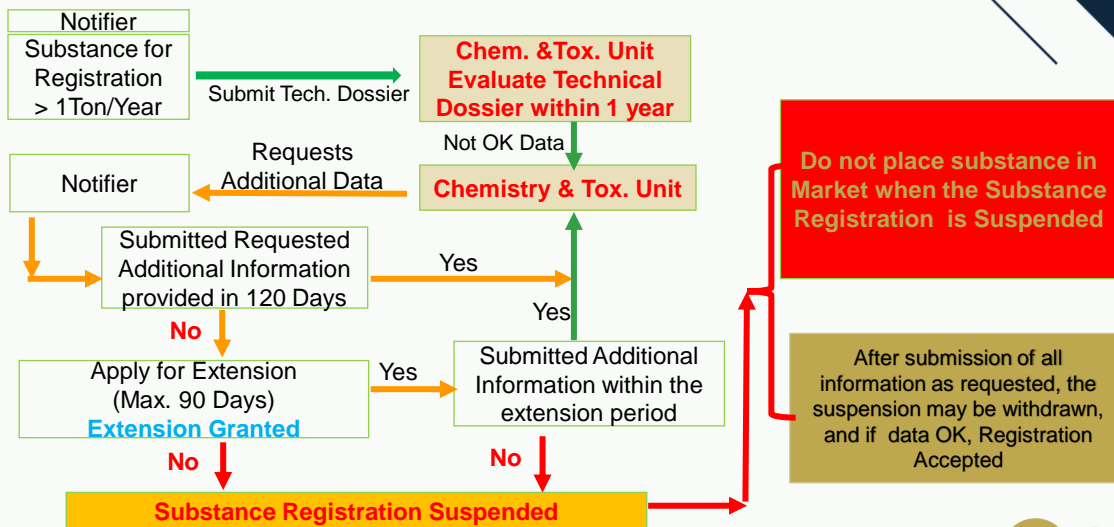
CSR Data Requirement: Schedule VIII

| CSR Sections (Schedule VIII) Required for > 10 Ton / Year | |
|--|--|
| Part I | |
| 1 | Summary of risk management measures |
| 2 | Declaration that risk management measures are implemented |
| 3 | Declaration that risk management measures are communicated |
| Part II | |
| 1 | Identity of the substance and physical and chemical properties |
| 2 | Manufacture and uses |
| 3 | Classification and labelling |
| 4 | Environmental fate properties |
| 5 | Human health hazard assessment |
| 6 | Human health hazard assessment of physicochemical properties |
| 7 | Environmental hazard assessment |
| 8 | Persistent, Bioaccumulative and Toxic (PBT) and very Persistent very Bioaccumulative (vPvB) assessment |
| 9 | Exposure assessment |
| 10 | Risk characterisation |



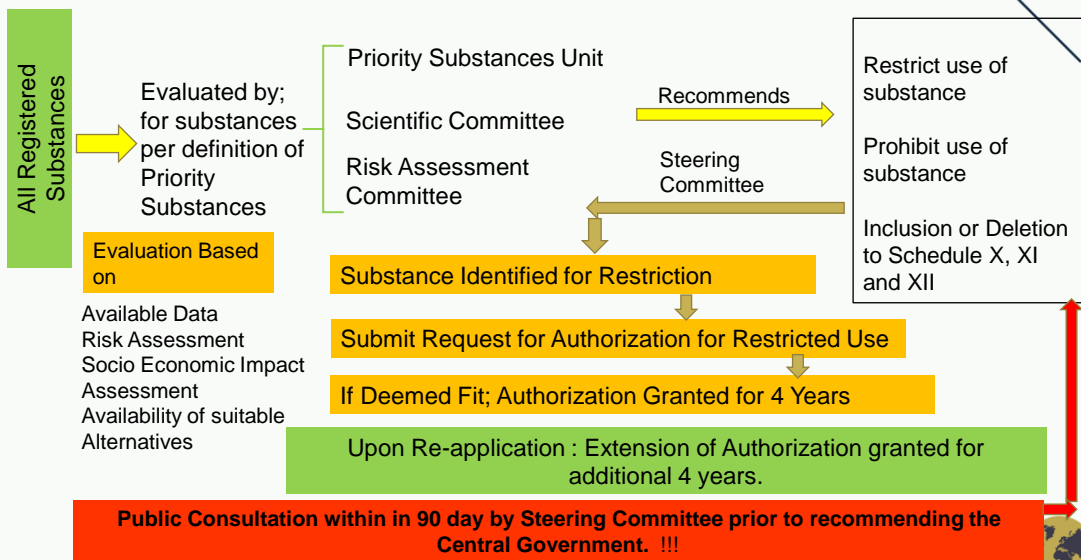
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Technical Dossier Evaluation Process



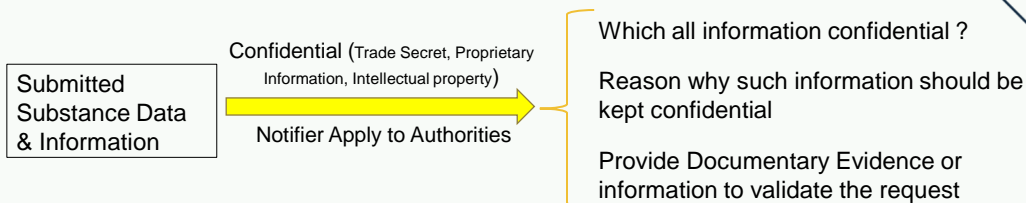
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CMSR – Evaluation & Restriction Process



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CMSR – Confidentiality of Information



Submitted information remain confidential till Techno Legal Team decides upon the Confidentiality Request.

Confidentiality granted for certain information remain confidential Even after the expiry of the term.

Confidentiality NOT Applicable for The Classification of Substance and the End Point Summaries Submitted. !!!



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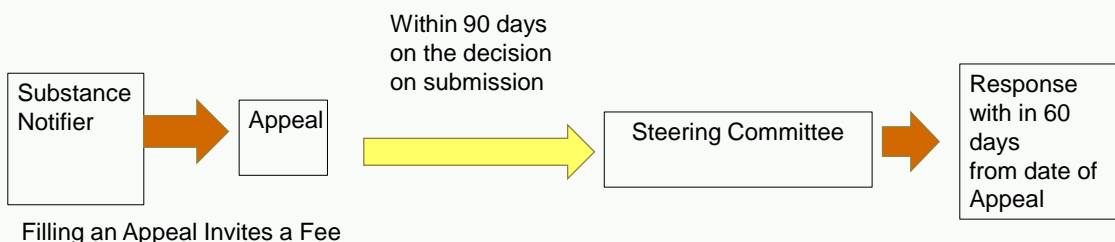
CMSR – Testing & Appeal

- Methodology and protocol as laid down by OECD for chemicals
- If Multiple testing options provided in OECD guideline for a substance;
 - Any of the option can be adopted
 - Concurrence of the Risk Assessment Committee Required.
- Testing to be carried out in
 - NABL accredited Labs or GLP Labs in India.
- To avoid repeated testing, the existing test data must be considered prior to requiring a new testing.
- All efforts should be made to derive the required data using alternative methods recommended by OECD.
- The Registrant must propose a testing strategy and get it approved by the Division before conducting any new test.
- Tests on vertebrate animals shall be undertaken only as a last resort.



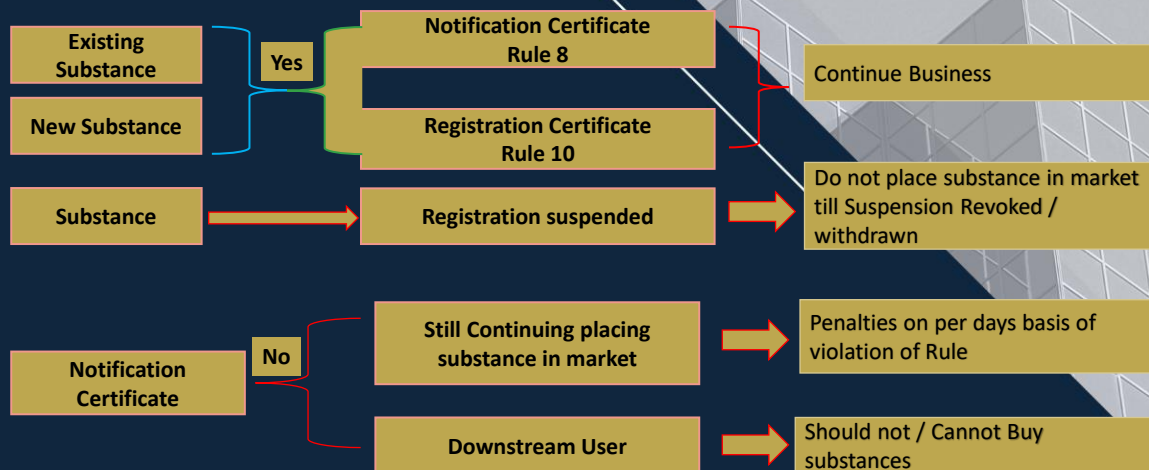
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CMSR – Testing & Appeal



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CMSR compliance



Do not Miss Notification & Registration Deadline once The Rule is into Force !!!



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Thank you.

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