



# 印度化学品法规 CMSR解读



全球化学品法规  
服务专家

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## 印度化学品市场

印度的化学和石化工业行业

预计到2025年，该行业规模将翻番

从1780亿美元（2018/2019年）增至3040亿美元。



四十多项法律条文



危险化学品



- Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules 1989
- Chemical Accidents, Emergency Planning, Preparedness and Response (CAEPPR) Rules 1996.



CMSR法规

## CMSR

英文全称：Chemical (Management and Safety) Rules

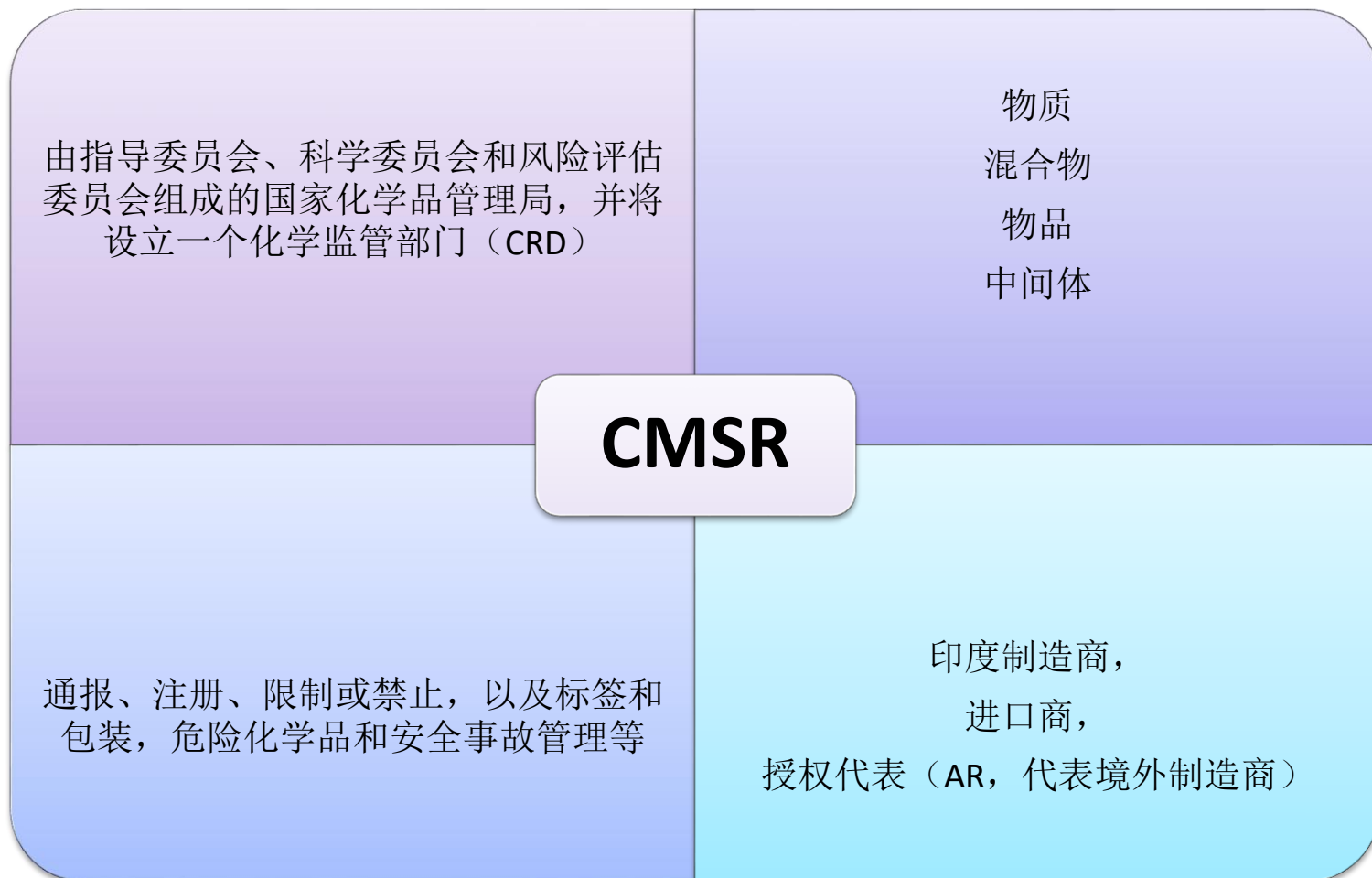
中文全称：化学品（管理和安全）条例

2020年8月24日，第五版草稿

预计在2021年年初开始生效，但尚未公布实施日期；生效后将对印度化学品生产贸易产生巨大影响



# CMSR-简介



# CMSR-外国制造商和授权代表



外国制造商/供应商需要委托一个印度法人实体作为授权代表（Authorized Representative, AR），以应对CMSR的合规要求。



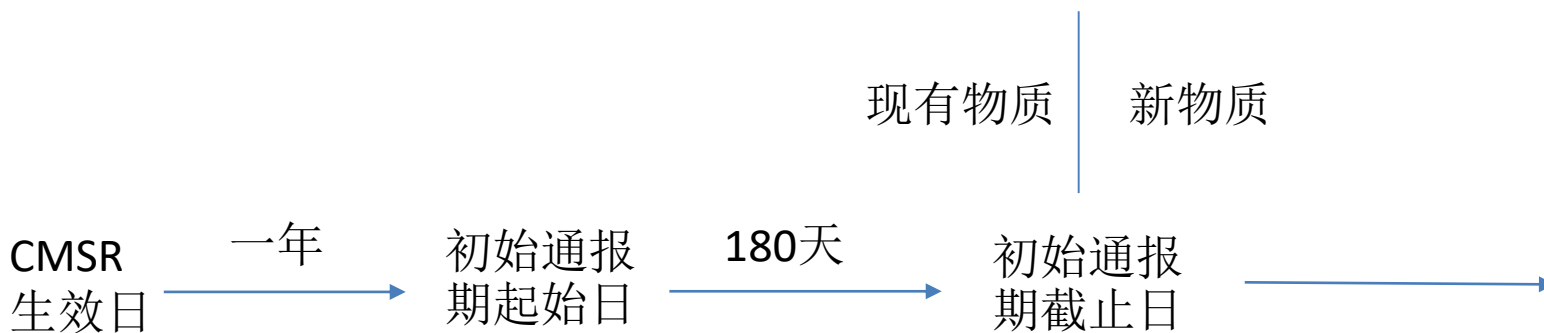
# CMSR-豁免

草案建议豁免下列事项：

- 1、放射性物质；
- 2、受海关监管的物质，未在印度上市；
- 3、为再出口目的而储存在免税区的物质；
- 4、废物，根据《2016年危险废物管理条例》定义；
- 5、用于国防目的的物质；
- 6、用作人或动物食物的物质，包括营养物质
- 7、草案附表IV所列的物质（目前包括15个条目）



聚合物没有明确豁免，  
可能会受到法规约束。



## 现有物质

- 在初始通报期截止日前，已经在印度制造、进口、供应或使用，投放的物质或中间体；
- 超过1吨/年的，需在初始通报期内完成通报。
- 在初始通报期截止日后，若要投放超过1吨/年的现有物质，需在投放前60天完成通报

## 新物质

- 在初始通报期截止日之后，在印度投放的物质
- 超过1吨/年的，需在投放前60天内完成通报

通报的数据要求

- a. 通报者详细信息
- b. 物质标识信息
- c. 杂质
- d. 物质结构信息和谱图
- e. 危害分类
- f. 用途
- g. 下游用户
- h. 吨位
- i. 最大存储容量
- j. SDS文件 (GHS Rev. 8):



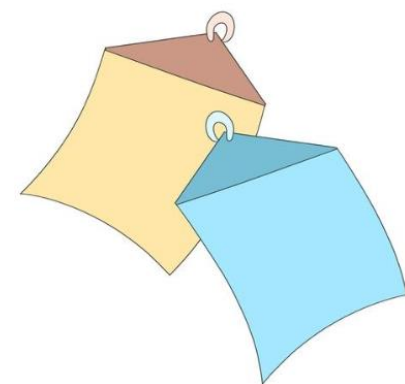
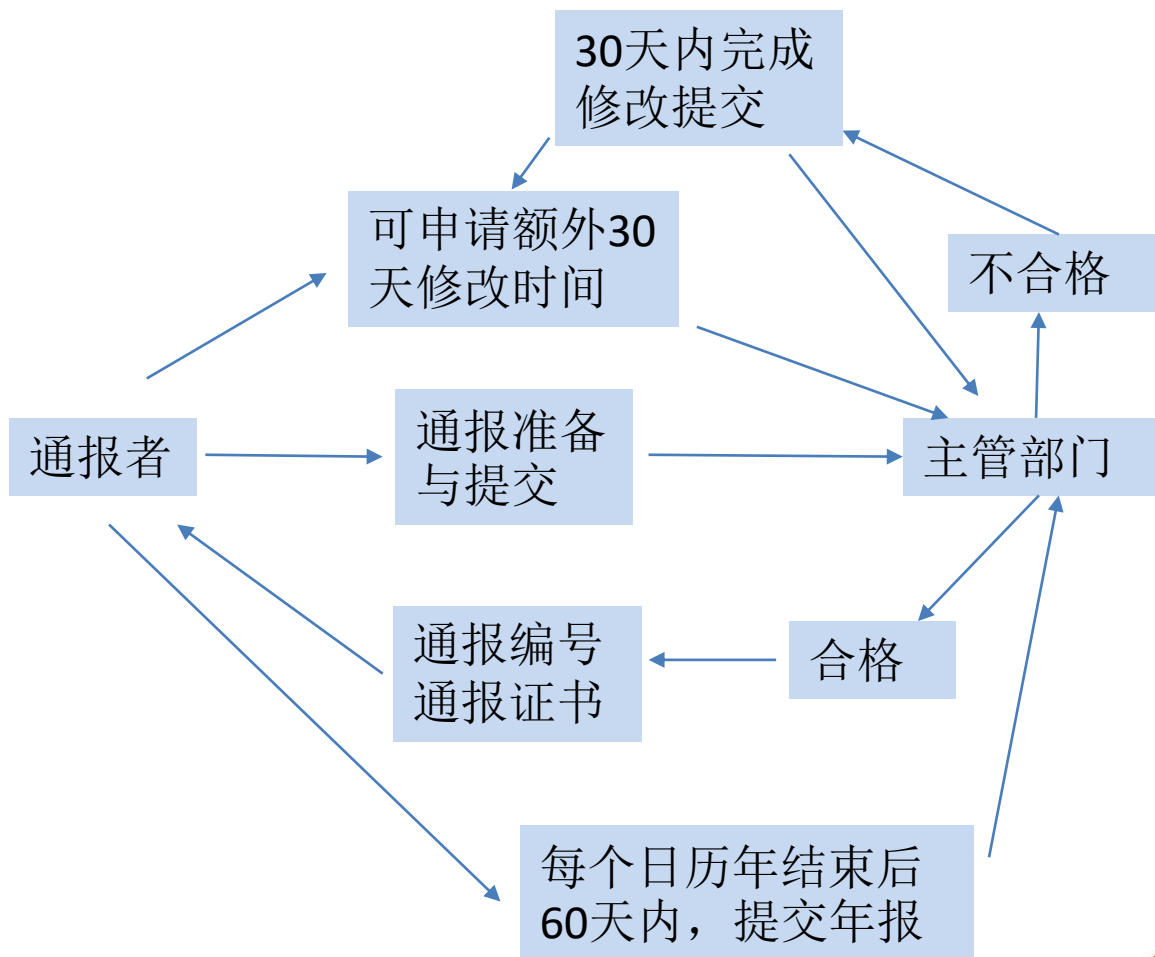
## Schedule V - Information to be provided for Notification

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.)

# CMSR-通报



# CMSR-年度报告



年报需要包含上一日历年投放到印度境内的吨位数量情况以及其他通报文件信息变化。

年报需要在每年2月29号(闰年)/3月1号前完成。



通报将是印度CMSR监管每年超过1吨的化学品的工具。

主管部门根据从通报过程及其评估中获得的信息，将确定进一步的监管措施，比如将一种物质归类为优先物质。

优先物质可能需要

注册



## CMSR-优先物质

优先物质是指符合法规条款2（hh）定义的物质，包括以下几个方面。

a. 根据UN GHS Rev.8具有以下分类：

1. 致癌性（Carcinogenicity）分类 I 类或 II 类，且/或
2. 致突变（Germ Cell Mutagenicity）分类 I 类或 II 类，且/或
3. 生殖毒性（Reproductive Toxicity）分类 I 类或 II 类，或
4. 特殊靶器官毒性 [Specific Target Organ Toxicity (Repeated Exposure or Single Exposure)] 分类 I 类或 II 类

b. 根据印度CMSR附表 I，属于持久性、生物积蓄性和毒性（Persistent, Bio-accumulative, Toxic, PBT）物质或极高持久性和极高生物累积性（very Persistent, very Bio-accumulative, vPvB）物质

c. 被列入附表 II “需要注册的优先物质”。目前有750个物质。

所有优先物质都有标签和包装要求（在进口前15天提交进口信息）  
只有被列入附表 II 的，超过1吨/年的优先物质才需要进行注册。

# CMSR-注册



- a. 超过1吨/年的优先物质
- b. 被列入附表II

1.5年

物品中的物质，被列入附表II，满足下面两个条件，则需要注册

- a. 可能会释放出来
- b. 超过1吨/年

注：物品中含量1% (w/w) 以上的物质被列入附表II，需要SDS

小于1吨/年的物质，可能被主管部门列入附表II，要求注册

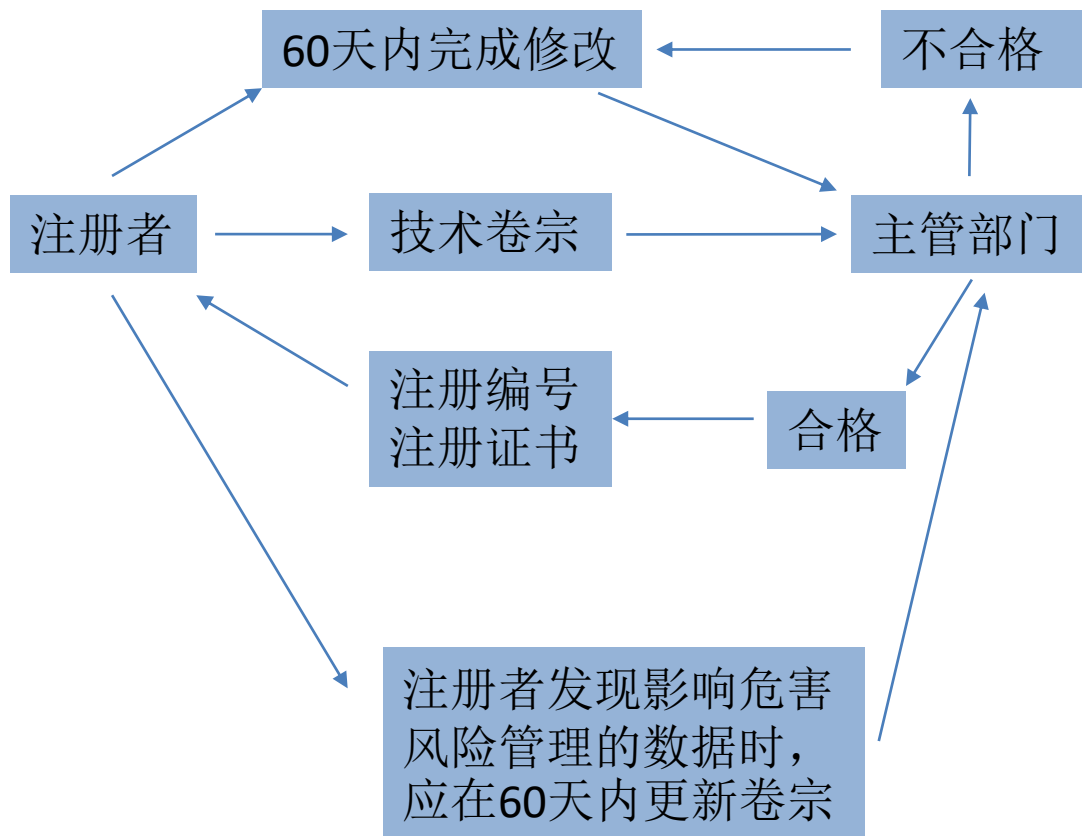
注册

相同物质

联合注册

- a. 含有相同主要成分且浓度超过80% (w/w)，且不含有浓度大于10% (w/w) 的被列入附表II的任何其他成分。
- b. 含有一种以上主要成分，且浓度在10% (w/w) 至80% (w/w) 之间的物质，如果它们具有相同的成分，则可视为同一种物质。
- c. 对于有未知或可变的成分、复杂反应产物或生物材料的物质 (UVCB)，主管部门将根据附表V第4a、4b和4c条中提供的信息来确定相同性。

# CMSR-注册



# CMSR-注册



## 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

注册者详细信息

### 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)

物质标识信息

### 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.

物质结构信息和谱图

### 4. Identified Chemical uses

- a) The calendar year of the registration

用途

- 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

分类和标签信息

### 6. Robust study summaries

研究摘要

### 7. Main use category:

- a) industrial use and/or
- b) professional use and/or
- c) consumer use

主要用途类别

### 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

主要暴露情况

### 11. Pattern of exposure:

- a) accidental/infrequent and/or
- b) occasional and/or
- c) continuous/frequent

化学品安全评估（Chemical Safety Assessment）

提交技术卷宗进行注册时，根据吨位可能还需要  
化学品安全报告（Chemical Safety Report, CSR）

- a. 大于10吨/年，列入附表Ⅱ的物质，注册时，需要提交完整CSR
- b. 1-10吨/年，列入附表Ⅱ的物质，注册时，至少要提交一个暴露场景



# CMSR-CSR



## Schedule VIII - Format for Chemical Safety Report

- Part I 风险管理措施总结和声明**
1. Summary of risk management measures
  2. Declaration that risk management measures are implemented
  3. Declaration that risk management measures are communicated
- Part II 物质信息**
1. Identity of the substance and physical and chemical properties
  2. Manufacture and uses  
2.1. Manufacture  
2.2. Identified uses  
2.3. Uses advised against
  3. Classification and labelling
  4. Environmental fate properties  
4.1. Degradation  
4.2. Environmental distribution  
4.3. Bioaccumulation  
4.4. Secondary Poisoning
  5. Human health hazard assessment  
5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)  
5.2. Acute toxicity  
5.3. Irritation  
5.3.1. Skin  
5.3.2. Eye  
5.3.3. Respiratory Tract  
5.4. Corrosivity  
5.5. Sensitisation  
5.5.1. Skin  
5.5.2. Respiratory system  
5.6. Repeated dose toxicity  
5.7. Mutagenicity  
5.8. Carcinogenicity  
5.9. Toxicity for reproduction  
5.9.1. Effects on fertility  
5.9.2. Developmental Toxicity  
5.10. Other effects  
5.11. Derivation of Derived No-Effect Level(s) (DNELs)
  6. Human health hazard assessment of physicochemical properties  
6.1. Explosivity  
6.2. Flammability  
6.3. Oxidising potential
  7. Environmental hazard assessment
- 7.1. Aquatic Compartment (including sediment)**  
**7.2. Terrestrial Compartment**  
**7.3. Atmospheric Compartment**  
**7.4. Microbiological Activity in Sewage Treatment Systems**  
**7.5. Derivation of Predicted No-Effect Concentration (PNEC)**
- 8. Persistent, Bioaccumulative and Toxic (PBT) and very Persistent very Bioaccumulative (vPvB) assessment**
- 9. Exposure assessment**
- 9.1. [Title of Exposure Scenario 1]  
9.1.1. Exposure Scenario  
9.1.2. Exposure Estimation
  - 9.2. [Title of Exposure Scenario 2]  
9.2.1. Exposure Scenario  
9.2.2. Exposure Estimation [etc.]
- 10. Risk characterisation**
- 10.1. [Title of Exposure Scenario 1]  
10.1.1. Human Health  
10.1.1.1. Workers  
10.1.1.2. Consumers  
10.1.1.3. Indirect exposure to humans via the environment  
10.1.2. Environment  
10.1.2.1. Aquatic Compartment (incl. Sediment)  
10.1.2.2. Terrestrial Compartment  
10.1.2.3. Atmospheric Compartment  
10.1.2.4. Microbiological Activity in Sewage Treatment Systems
  - 10.2. [Title of Exposure Scenario 2]  
10.2.1. Human Health  
10.2.1.1. Workers  
10.2.1.2. Consumers  
10.2.1.3. Indirect exposure to humans via the environment  
10.2.2. Environment  
10.2.2.1. Aquatic Compartment (incl. Sediment)  
10.2.2.2. Terrestrial Compartment  
10.2.2.3. Atmospheric Compartment  
10.2.2.4. Microbiological Activity in Sewage Treatment Systems

环境危害评估

PBT,vPvB评估

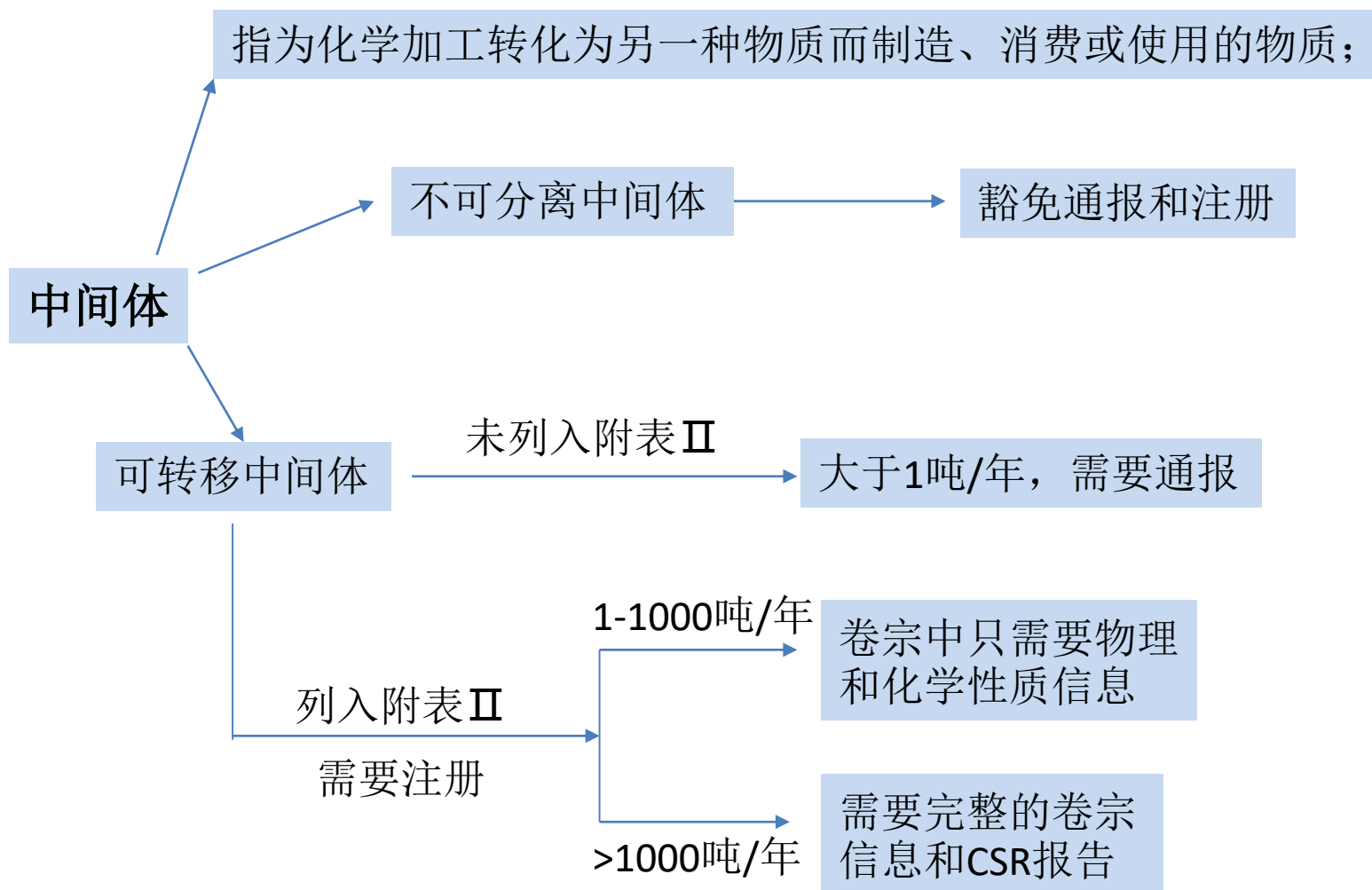
暴露场景评估

风险特征分析

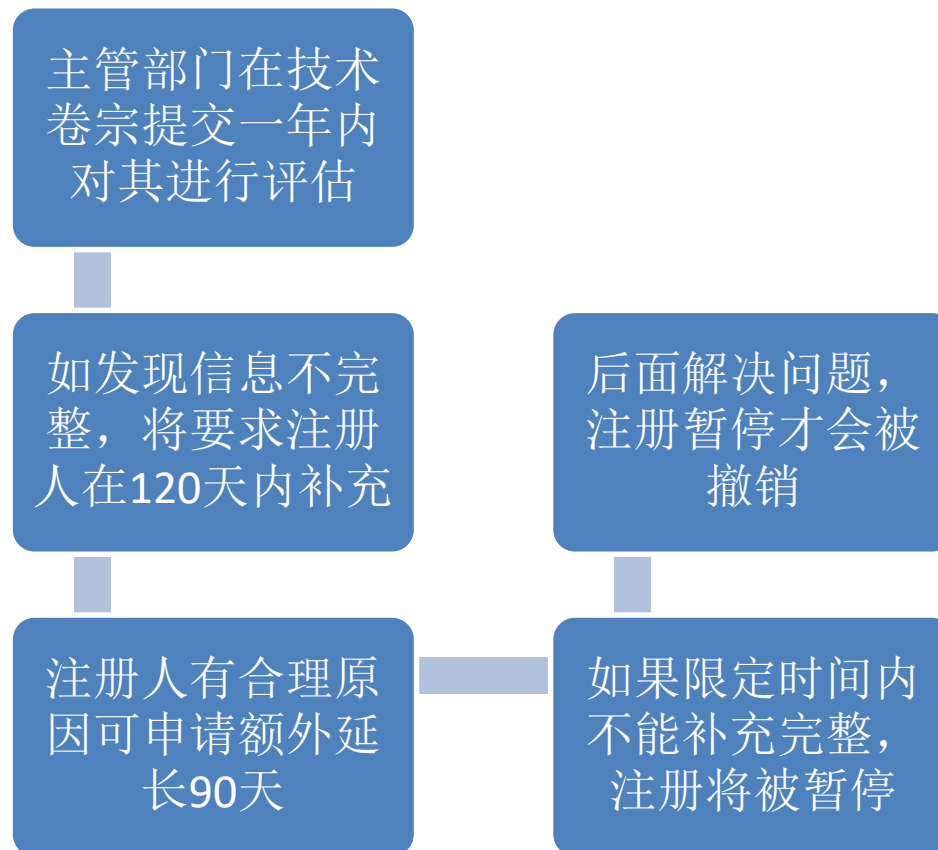
健康危害评估中的物理化学信息

*(If desired, Sections 9 and 10 may be combined into one Section without loss of information)*

# CMSR-中间体



# CMSR-卷宗评估



# CMSR-限制或禁止

主管部门将评估现有数据，以评估优先物质在各种使用过程中是否对人类安全或环境构成不可接受的风险。

如果使用该优先物质所造成的风险很大，则可建议限制或禁止使用该物质，列入附表VI，也可能建议其列为危险化学品。

要使用受到限制的物质，需要向主管部门提出授权使用该物质的请求。根据草案，成功获得授权的，可以批准使用四年。

Schedule VI – Restricted or Prohibited Substances

Sr. No.	Chemical Name	CAS No.	Category
1	Phosgene 光气		Restricted

优先物质；危险化学品；混合物中含有超过10%的优先物质或危险化学品

制造商、进口商或下游用户需要确保标签正确醒目，包装合格安全

## Schedule XVII - Information in Labelling

A Priority Substance in packaging shall bear a label including the following elements:

1. The name, address and telephone number of the manufacturer, importer or downstream user
2. The nominal quantity (with +/- 5% accuracy) of the Priority Substance or Hazardous Chemical in concentration of greater than 0.1% (w/w) in the package made available to the general public, unless this quantity is specified elsewhere on the package
3. Product identifiers
4. Hazard pictograms where applicable
5. Signal words, where applicable
6. Hazard statements, where applicable,
7. Appropriate precautionary statements, where applicable
8. A section, where applicable
9. IN Number as assigned by the Division

*(All information shall be in accordance to the eighth revision of UN-GHS Classification)*



## CMSR-处罚

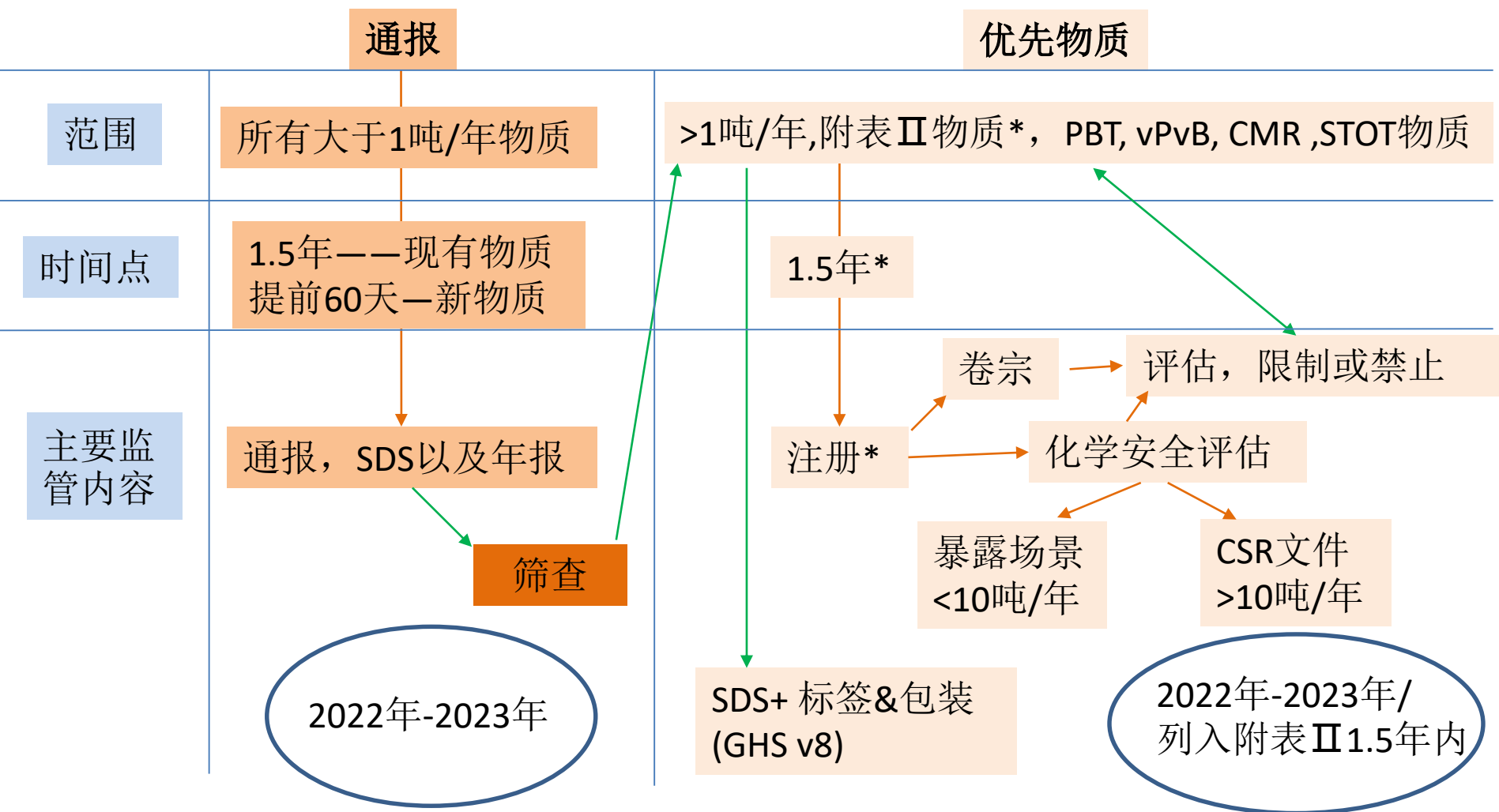
对于违反法规的情况，例如

- (a) 未能在规定时间内对物质或中间体进行通报或注册；
- (b) 在通报或注册时提供虚假信息；
- (c) 下游用户采购未经通报或注册的物质、混合物、中间体或物品；
- (d) 优先物质的标签或包装不符合规定

须按持续违反的每一天处以相应的罚款。

吨位	持续违反的每一天处以 罚款 (印度卢比, Rs)	换算成人民币
1-1000 t/a	25000	2222.75元
>1000 t/a	50000	4445.5元





项目	CMSR	EU-REACH
预注册	无	有（已经结束）
通报和年报	有	无
注册	列入附表II的物质（现有750个），吨位超过1吨/年	新物质和现有物质，吨位超过1吨/年
聚合物注册	未知，可能会包括	目前按单体注册 （考虑聚合物注册的立法）
数据要求	原则类似，具体未知	吨位越高，数据要求越高
委托代表概念	有，授权代表AR	有，唯一代表OR
SDS	需要	需要
卷宗评估	有	有

本条涉及8月24日的新法规草案。

以后可能会有一些补充，例如关于一般物质是否需要注册，聚合物豁免与注册方式，具体的数据要求和相关费用的澄清等等



一旦生效，企业将只有**18个月**的时间来满足大多数合规要求。

因此，建议企业要及早了解产品合规要求，准备相关数据信息。

- a. 成立监管团队
- b. 建立物质清单并及时更新
- c. 确认进入印度的数量
- d. 开始与下游用户进行联系沟通
- e. 根据GHS Rev.8更新SDS
- f. 及时了解最新的CMSR信息
- g. 内部培训CMSR



待法规生效日确定后，及时完成合规要求

- 印度化学品（管理和安全）条例CMSR下合规分析，咨询及培训

- 印度以外企业授权代表（AR）授权及委托

- >1吨/年化学物质通报，优先物质注册

- 年度报告的准备及递交和SDS制作

- 测试数据方案准备等



# Thank You!



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