

Draft Indian Chemical Management and Safety Rules (CMSR), 20xx (India-REACH)

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About GPC

Global Product Compliance (GPC) specializes in Global Regulatory Compliance Solutions across sectors globally. SSS Europe, a familiar name in chemical regulatory and compliance services now formally belongs under the umbrella of GPC Holding Sweden.

Since 2008, we have emerged as one of the leading names among Global Regulatory Compliance Service Providers with Representation services in Europe, Asia and Middle East for respective chemical regulations.

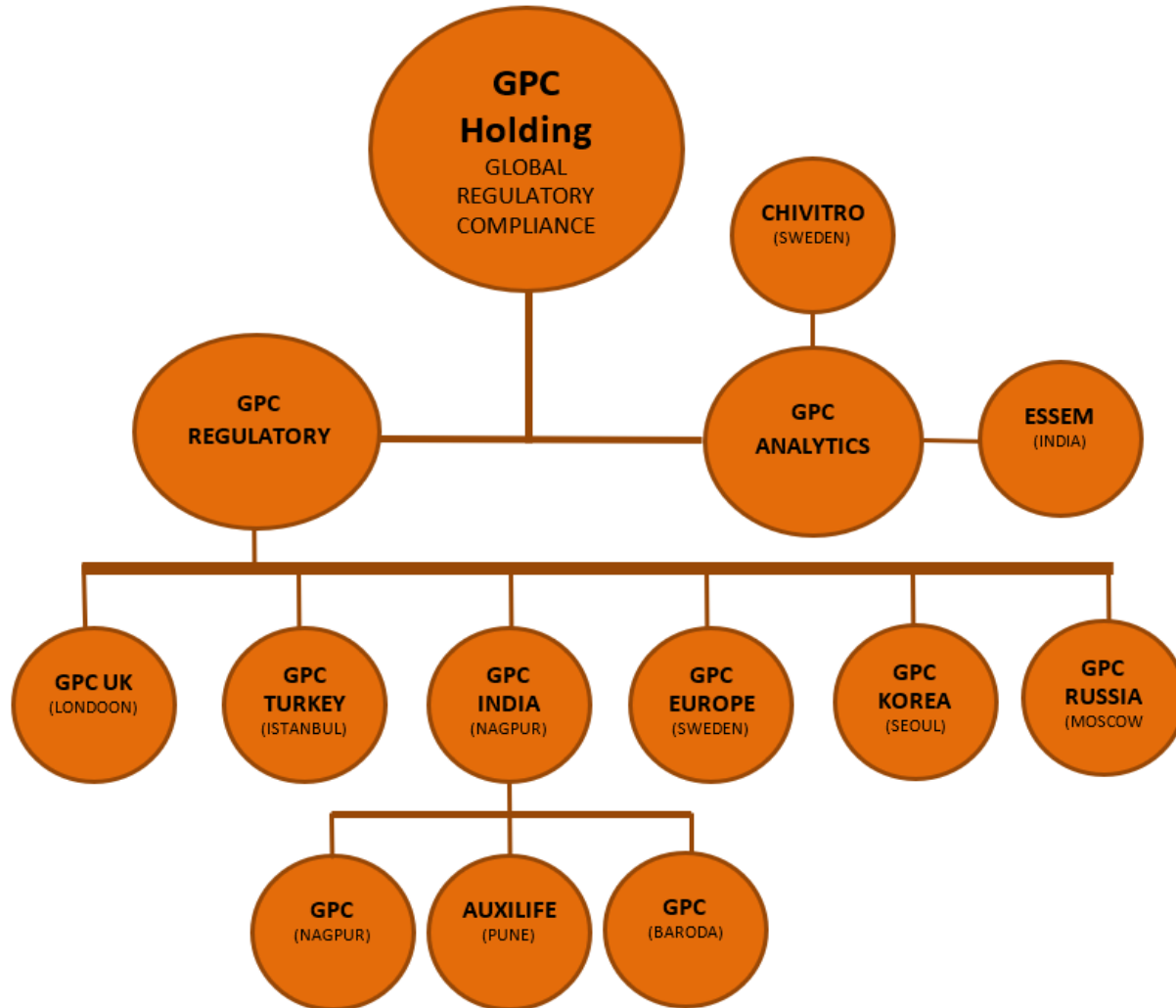
Our over 1000 Happy Clients are a testimony to the great rapport we share with them and the fine quality that we offer in our services. This is also reflected in the fact that we have about 99% customer retention.

AGENDA

India CMSR – India REACH (5th Draft - 24 Aug 2020)

- GPC in brief and GPC's engagement in Indian CMSR
- ICMSR – Key words, Objective, Scope, and Authorities
- Chapters & Related Schedules
- Timeline and Obligations under ICMSR
- Fees : Notification, Registration
- Actionable for PSCI members (Overseas and Indian) & Importers
- GPC : Your Knowledge Partner toward ICMSR compliance
- Interaction (Q&A)

Global Product Compliance (GPC)



- Indian Chemical (Management and Safety) Rules (ICMSR)
- EU-REACH
- Korea-REACH
- Eurasia REACH
- Turkey REACH (KKDIK)
- UK-REACH
- Taiwan Regulation (TCSCA)
- Chemical Regulations in USA, Canada, Australia, Thailand, China, Japan & Brazil.
- Cosmetics Regulation (EU, India, USA).

1000+ Happy Clients.
99% Customer retention
172+ companies opted to switch over to GPC

Global Product Compliance (GPC)

Services

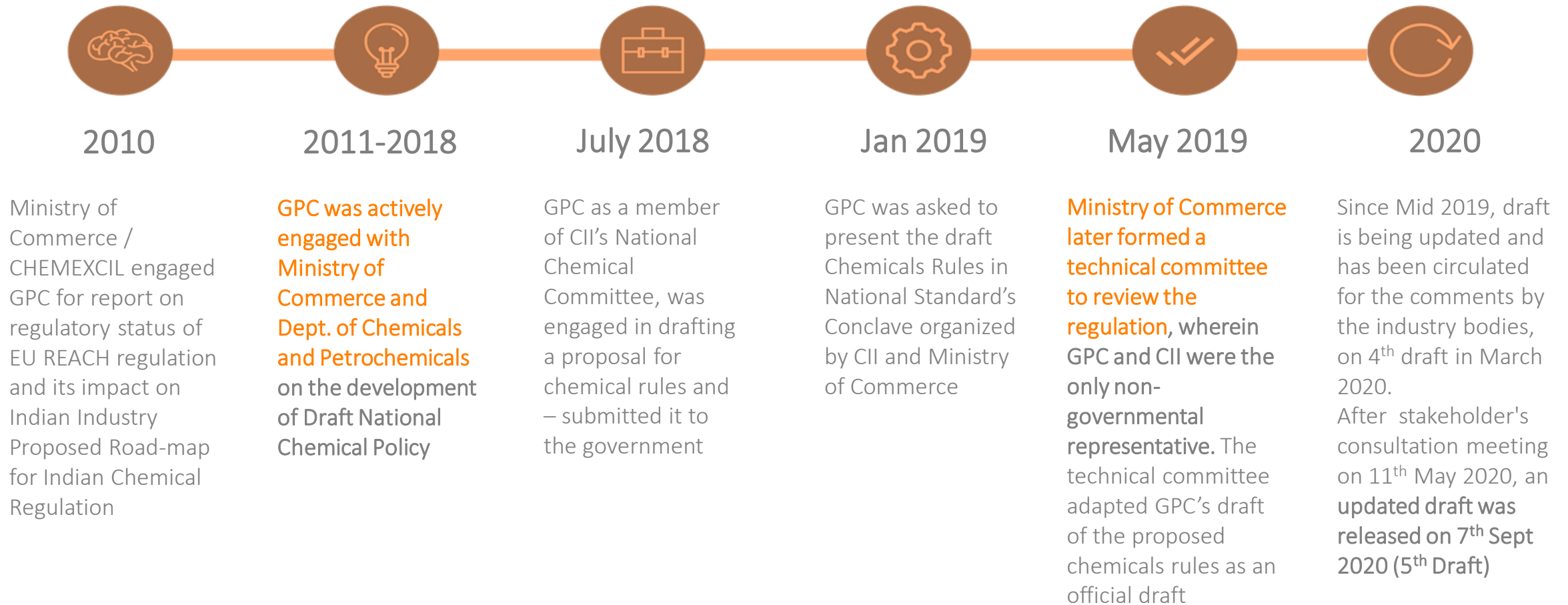
- Registrations & Notifications
- Global Regulatory Compliance & Status Assessment
- Substance & Dossier Evaluation Process Management
- Lead Registration activity & Technical dossier preparation
- Toxicological assessment & Dossier updates
- Contract Study Management & Monitoring
- Compliance Verification & Certificates
- REACH & CLP compliant SDS & Extended e-SDS
- SDS translations in over 30 languages

Services – Key facts

- **Managed portfolio of 9000+ substances.**
- **Registered 1200+ substances.**
- Lead Registration & consortia management of **400+** substances.
- **9000+** pre-registrations and notifications within chemical and cosmetic regulations, globally.
- Authored **4200+** REACH & CLP compliant SDSs and **320+** e-SDSs.
- Extensive network of OECD-GLP certified CROs.
- **‘Supply Chain Communication Portal’ for seamless regulatory communication** and due diligence – between supplier, buyer, and OR. The portal is used by **4000+** users.

GPC provide regulatory intelligence to industry and prepare industry for the compliance requirements & related challenges!

GPC Engagement with Indian CMSR



ICMSR – Key words, Objective, Scope, Authorities

Key Words	Substance ; Substance in Mixture; Mixture; Articles; New Substance, Existing Substance; Priority Substance ; Hazardous Substance; Chemical Accident; Intermediates ; Isolated Storage ; Industrial Activity; Occupier ; Manufacturer ; Importer	
Objective & Scope	Notification, Registration and Restrictions, or prohibitions, as well as labelling and packaging requirements related to the Use of Substances..... Placed or intended to be Placed in Indian Territory	
	Provide safety procedures for the Manufacture, handling and Import of Hazardous Chemicals and preparedness and management of Chemical Accidents; Ensure a high level of protection to human health and the environment.	
Authorities	<p>The National Chemical Authority with 4 key organs to implement the Rules:</p> <ul style="list-style-type: none"> • Steering Committee • Scientific Committee • Risk Assessment Committee • 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

India Chemicals (Management & Safety) Rules

Chapter	Title
I	Definitions, Objective & Scope
II	National Chemical Authority
III	Notification Registration & Restrictions on Use
IV	Safety & Accident Preparedness
V	Labelling & Packaging
VI	Miscellaneous (Penalties and Enforcement)

India Chemicals (Management & Safety) Rules

Schedule	Title
I	PBT & vPvB Assessment Criteria
II	List of Priority Substances required to be Registered (750 Subs.)
III	Concerned Authorities
IV	Substances Exempted for the purpose of Chapter III and V
V	Information to be provided for Notification
VI	Restricted or Prohibited Substances (Phosgene 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 ...) 20 identified
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

Timeline & Obligation under ICMSR



Notification Of Substances \geq 1 ton/year



Registration of Schedule II Chemical Substance (**750**) \geq 1 ton/ year



Evaluation Of files and Substances



Restriction & Prohibition Of Unacceptable Substances



Authorization Of Substances of concern by Committee



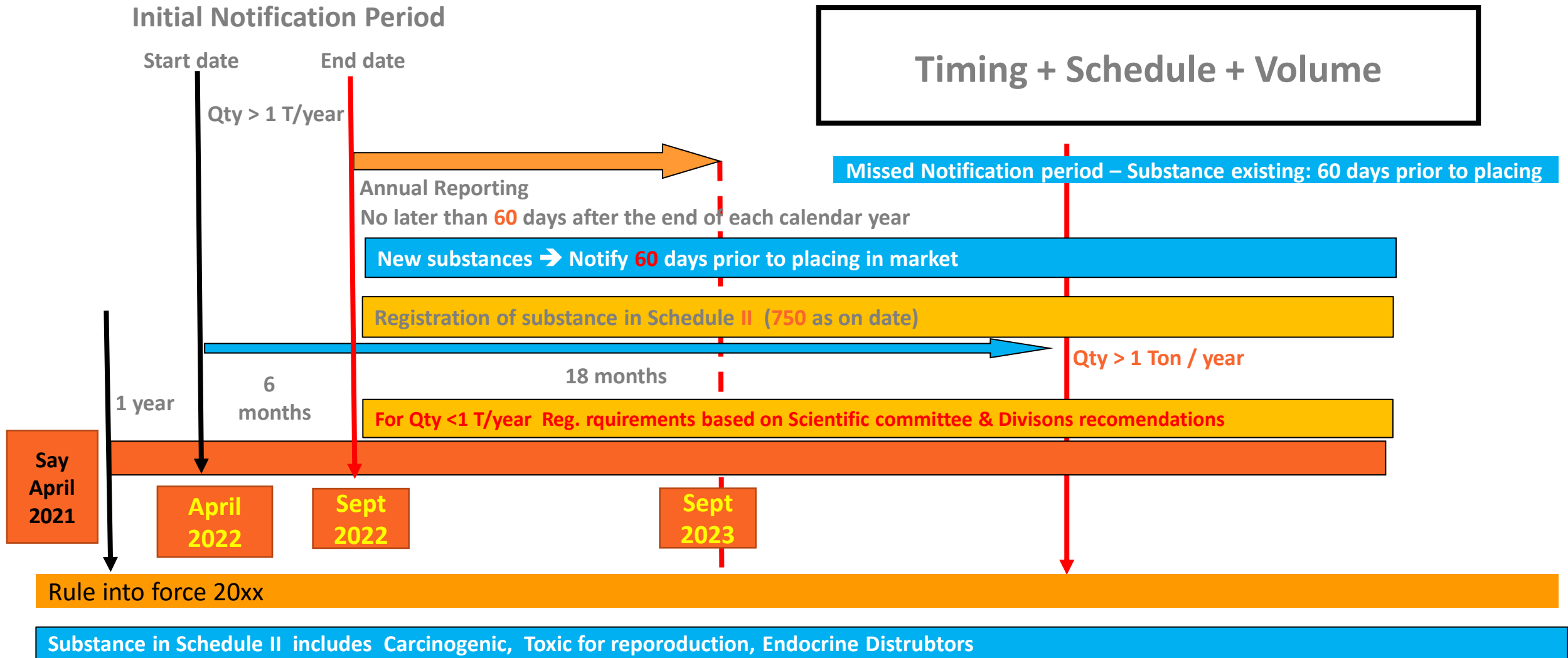
Annual Reporting - No later than 60 days after the end of each calendar year

Information in the supply chain



Chemical Properties & Uses : Up & down - Supply chain

Timeline & Obligation under ICMSR



Fees : Notification & Registration

Approx.: Fees for Notifiers and Registrants (Rs. ' 000)

Sr. No.	Rule		Payable entity (MSMEs)	Payable by all other entities	
1	8 (5)	Notification by tonnage band	1-10 TPA	10	25
			10- 100 TPA	30	75
			100 - 1000 TPA	80	200
			> 1000 TPA	250	600
2	10 (10)	Registration by tonnage band	1-10 TPA	15	37
			10- 100 TPA	45	112
			100 - 1000 TPA	120	300
			> 1000 TPA	375	900
3	16 (5)	Request for authorization for use of a restricted substance	1000	1000	
4	17 (3)	Request for confidentiality	5	100	
5	19 (4)	Filing an appeal	10	100	

Fees : Update Notification & Registration

Approx.: Fees for Updating tonnage band in notification and registrations
(Rs. ' 000)

Sr. No.	Rule		Payable entity (MSMEs)	Payable by all other entities
1	8 (5)	Updating tonnage band		
		From 1- 10 TPA To 10 - 100 TPA	20	50
		From 1- 10 TPA To 100 - 1000 TPA	70	175
		From 1- 10 TPA To > 1000 TPA	240	575
		From 10- 100 TPA To 100-1000 TPA	50	125
		From 10- 100 TPA To >1000 TPA	220	525
		From 100- 1000 TPA > 1000 TPA	170	400

Fees : Joint Registration

Approx.: Fees for Joint Registration per Registrant (RS. '000)

Sr. No.	Rule	Tonnage band	Payable entity (MSMEs)	Payable by all other Entities
1	10 (10)	1-10 TPA	10	25
		10- 100 TPA	30	75
		100 - 1000 TPA	80	200
		> 1000 TPA	250	600

Joint Registration is valid for the same substance !!!

Actionable for PSCI members

- Indian Manufacturer / Importer / DU : Follow guideline and be a Notifier
- Overseas Manufacturer :

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

Foreign Traders may not appoint an Authorized Representative

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

Actionable for PSCI members - Notification



Notify all substances that are placed in Qty > 1 TPA



Notification is not Free



Key data required: Spectra, Hazard Classification, Uses, DU if any, Tonnage Band, Storage Capacity, SDS (Rule 9(2))



Annual update by **1st March** each year – tonnage (actual); new/change information; if tonnage change (fee difference)



Registration within other regulations / Acts – are also required to Notify with ICMS Rules

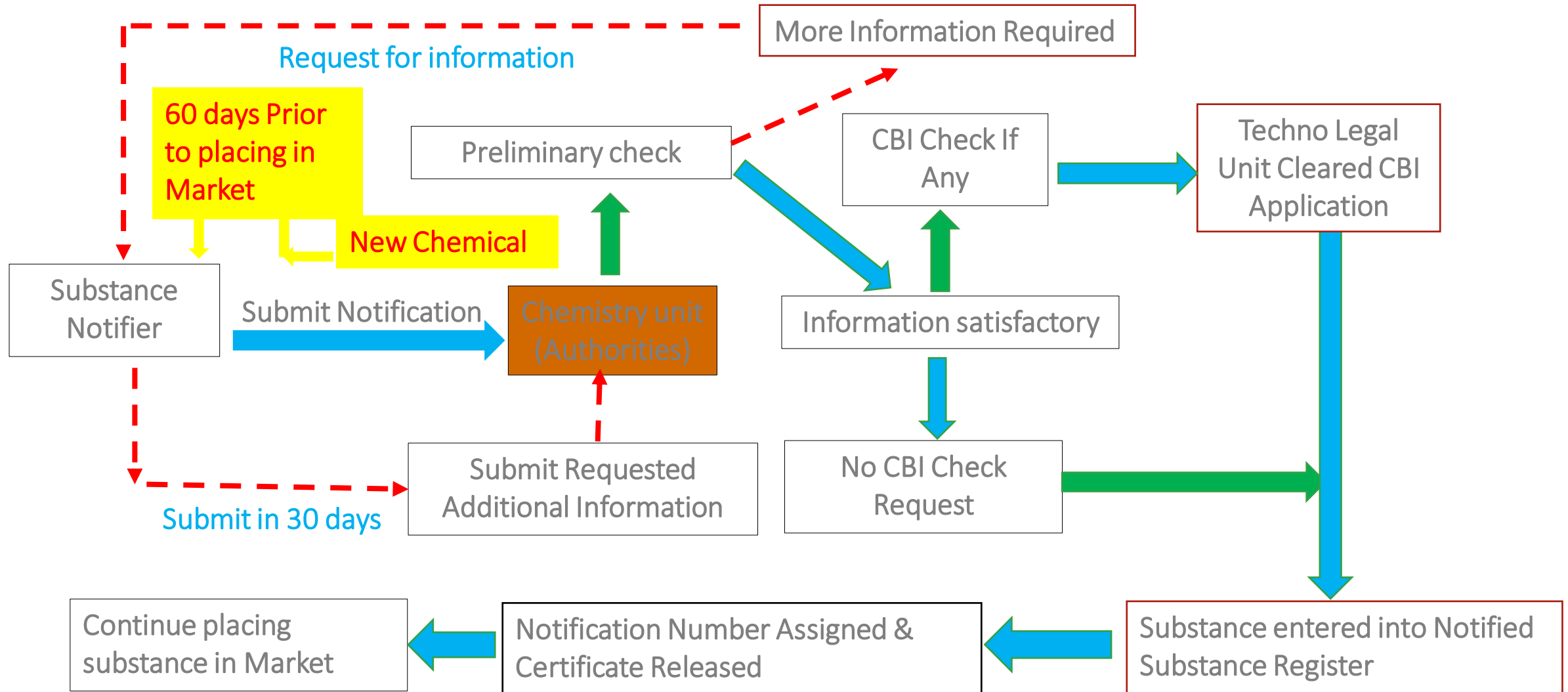


Late Notification

New Substance (**60** days prior to placing)

Existing Substance: **if missed notification window – 60 days prior to placing it in market.**

Notification Process:

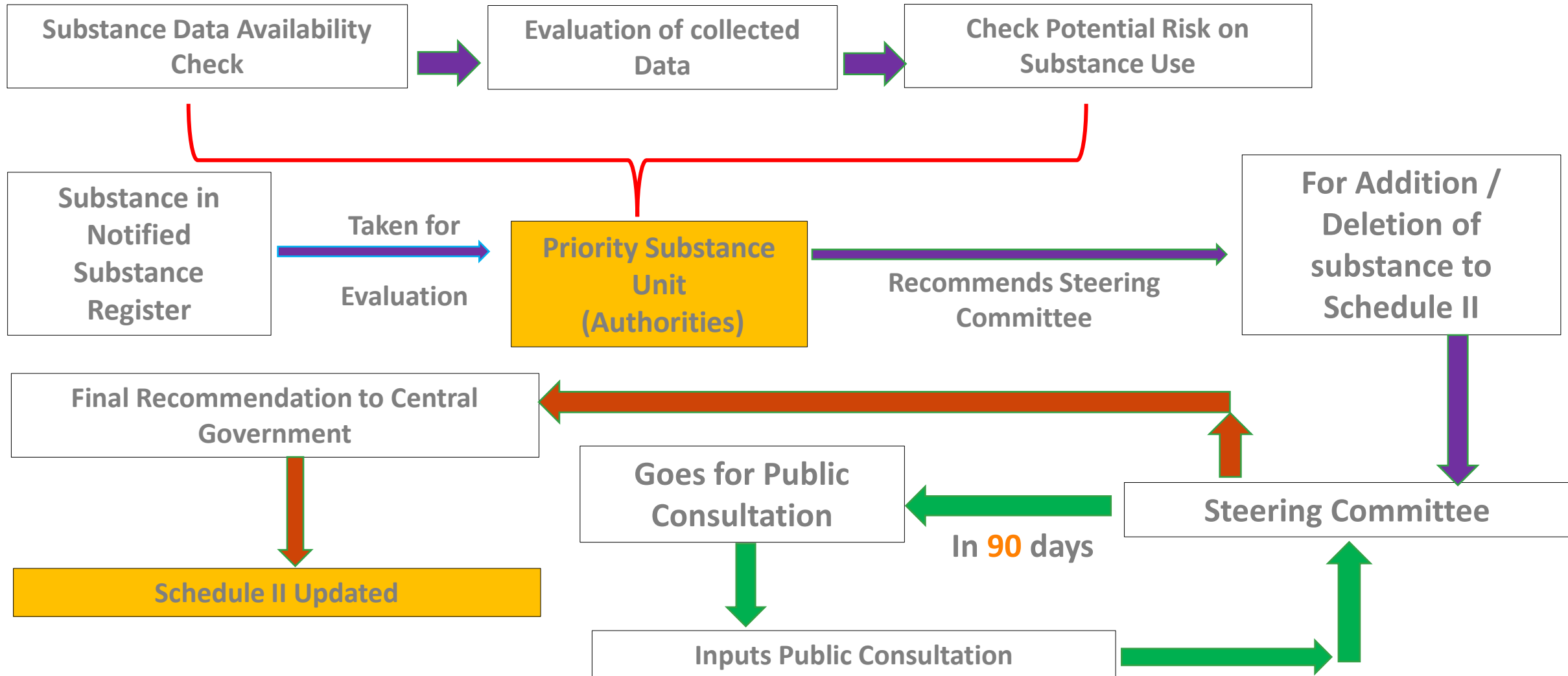


Actionable for PSCI members - Notification

Substances that are notified within the “Initial Notification Period” are considered as Existing Substances

All substances that are not notified in the Initial Notification Period are considered as New Substances.

Evaluation Process : Post Notification



Actionable for PSCI members - Registration



Registration -
Substances listed in
Schedule II
Priority Substances



Registration within
18 months after
inclusion in
Schedule II



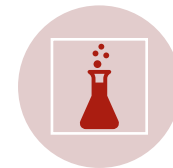
Currently Schedule II
contains **750** substances.



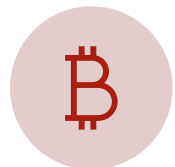
Technical Dossier
needs to be
prepared.



Chemical Safety
Assessment
(report) for > 10
TPA.



Exposure Scenario
Assessment
(report) for < 10
TPA.



Registration fee is
applicable –
Company Size &
Tonnage



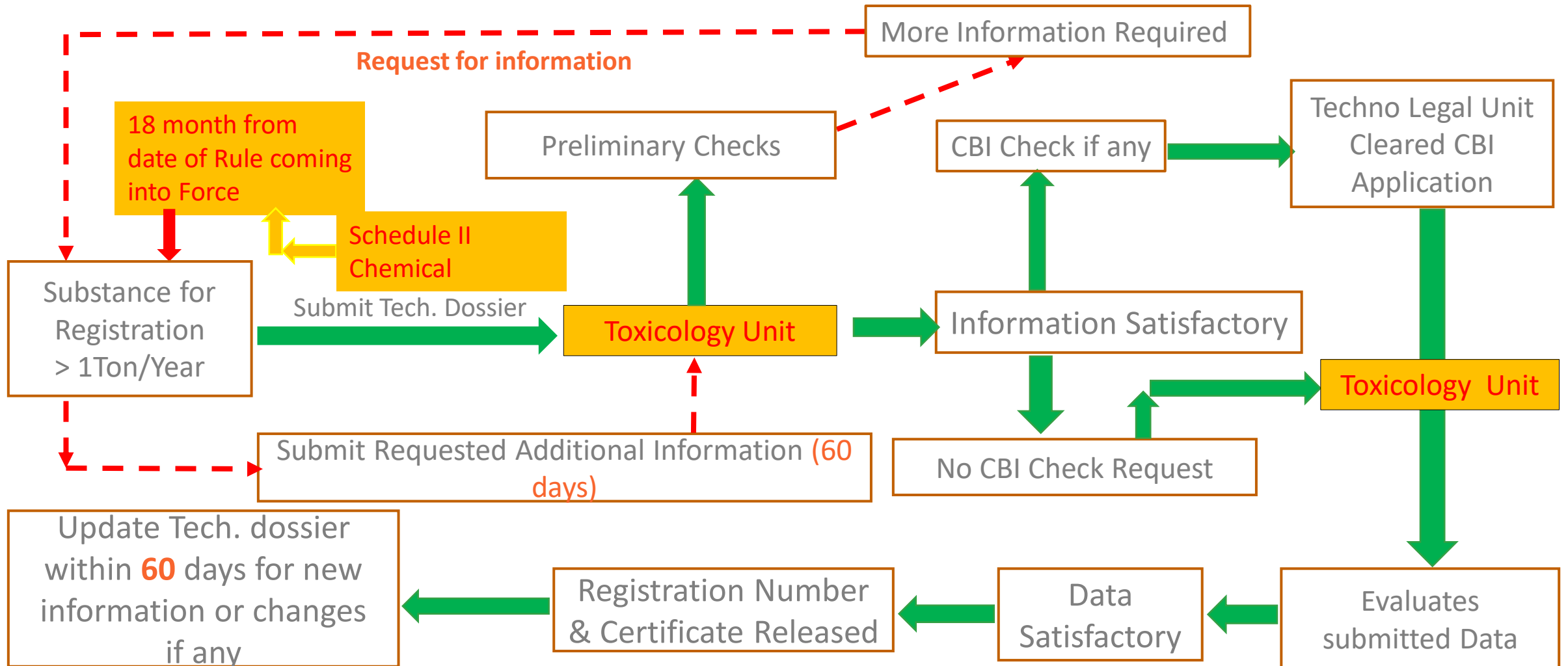
Option to jointly
submitting the
registration,



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

Joint Registration is valid for the same substance!

Actionable for PSCI members : Registration process



Actionable for PSCI members – Priority Substance



Currently 750 substances are listed as Priority Substances in Schedule II. – Notify & Register



Schedule II will be updated from time to time



labeling and packaging requirements (Rules 33 & 34)



Import of Priority substances: Inform Authority **15** days before importation. (Rule 27)



Certain Priority Substances may qualify as – Hazardous Substances (Rule 16(3))

Actionable for PSCI members – Restriction(VI)

Substances that are Listed in Schedule VI: Restricted or Prohibited Substances

As on today only one substance restricted : Phosgene (carbonyl chloride)

Actionable for PSCI members : Evaluation & Restriction Process



Actionable for PSCI members – Transported Intermediate



Transported Intermediates - Substances listed in Schedule II



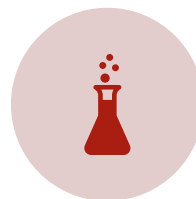
< 1000 TPA (Only Phys - Chem data in Technical Dossier)



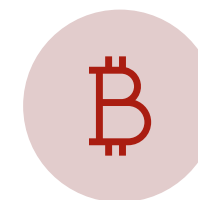
> 1000 TPA (full Registration and Chemical Safety Report)



Intermediates not in Schedule II



No Registration obligation



Only Notification obligation

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

But to be Notified!

Actionable for PSCI members – Hazardous substance

⚠️ Currently 669 substances are listed as Hazardous Chemical List in Schedule X. -- Notify

🕒 Schedule X will be updated from time to time

✓ labeling and packaging requirements (Rules 33 & 34)

⊖ Provide Evidence to Authorities that they have identified the Chemical Accident hazards
Adequate Steps taken to prevent accidents & to limits its impact

⊖ Evidence shall be provided within 30 days of commencement of the activity or within 30 days of coming into force of these Rules, which ever is later.

✓ Obtain an Acknowledgement from Authority with 60 days

Actionable for PSCI members – Occupier Notifies Industrial Activity



Transport –Tracking & Communication System; Labeling, give prior intimation the State Pollution Control Boards



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



Site Safety Report (New industrial activity - 90 days before) – Steps in accident prevention; Provide information, training, equipment and antidotes – to Employees; and Get Approval from Authorities



Isolated storage and quantity Thresholds (Schedule XI & XIII - industrial installations)

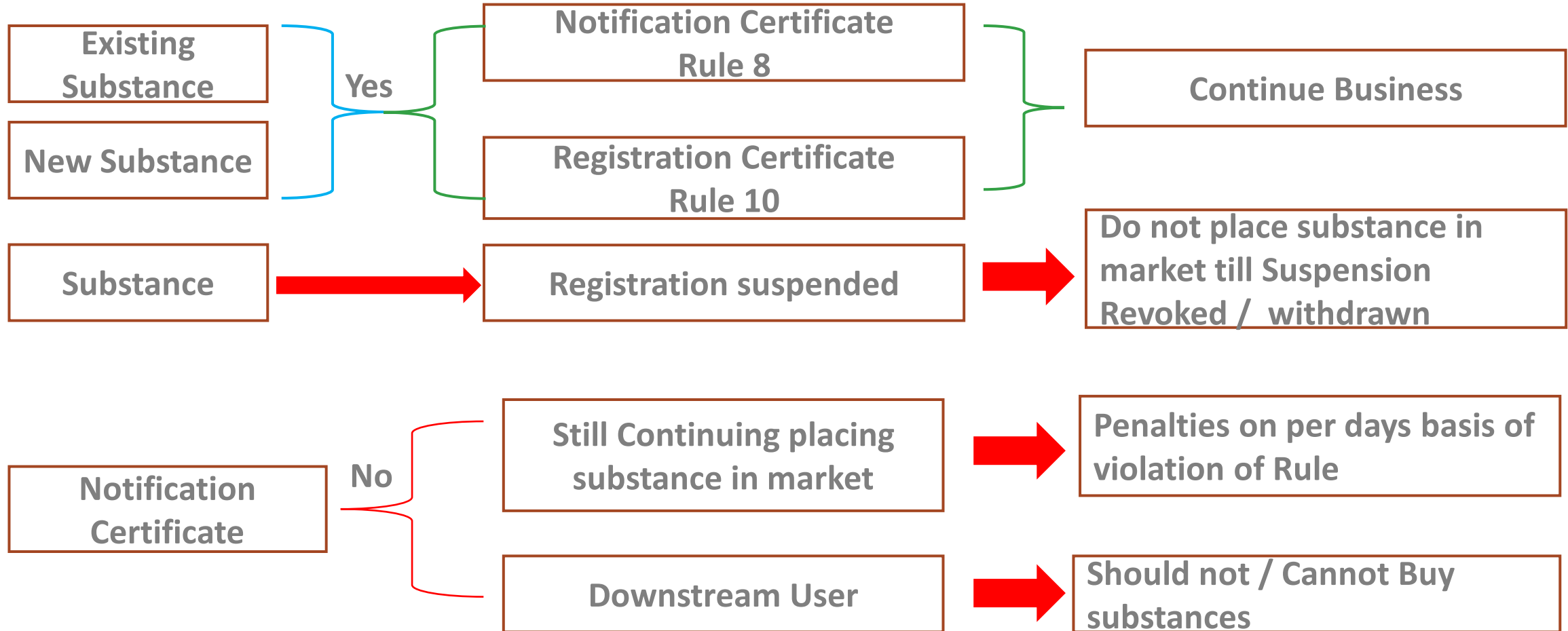


Onsite / off-site Emergency Preparedness Plan within 3 months; (on-site - mock drill every 6 month)



Notification of Accident within 24 hrs.; report within 72 hrs. Report on preventive action with 6 months of accident

GPC : Your Knowledge Partner - ICMSR compliance



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



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About the Secretariat

Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

