

Chemical Management in the US

- ◇ *General Introduction of TSCA*
- ◇ *Amended TSCA*
- ◇ *Amended TSCA & Current Status*
- ◇ *Others*



Chemical Management in the US

TSCA (Toxic Substances Control Act)

Enacted: October 11, 1976

Effective: January 1, 1977

Administered: United States Environmental Protection Agency (EPA)



In 40 years..., amended on June 22, 2016

United States Code (U.S. Code) : Title 15 - Commerce and Trade

Chapter 53 - Toxic Substances Control Act

The Code of Federal Regulations (CFR) : Title 40 - Protection of Environment

TSCA - General Introduction

When you manufacture or import your chemical substance in the U.S. for commercial purposes,



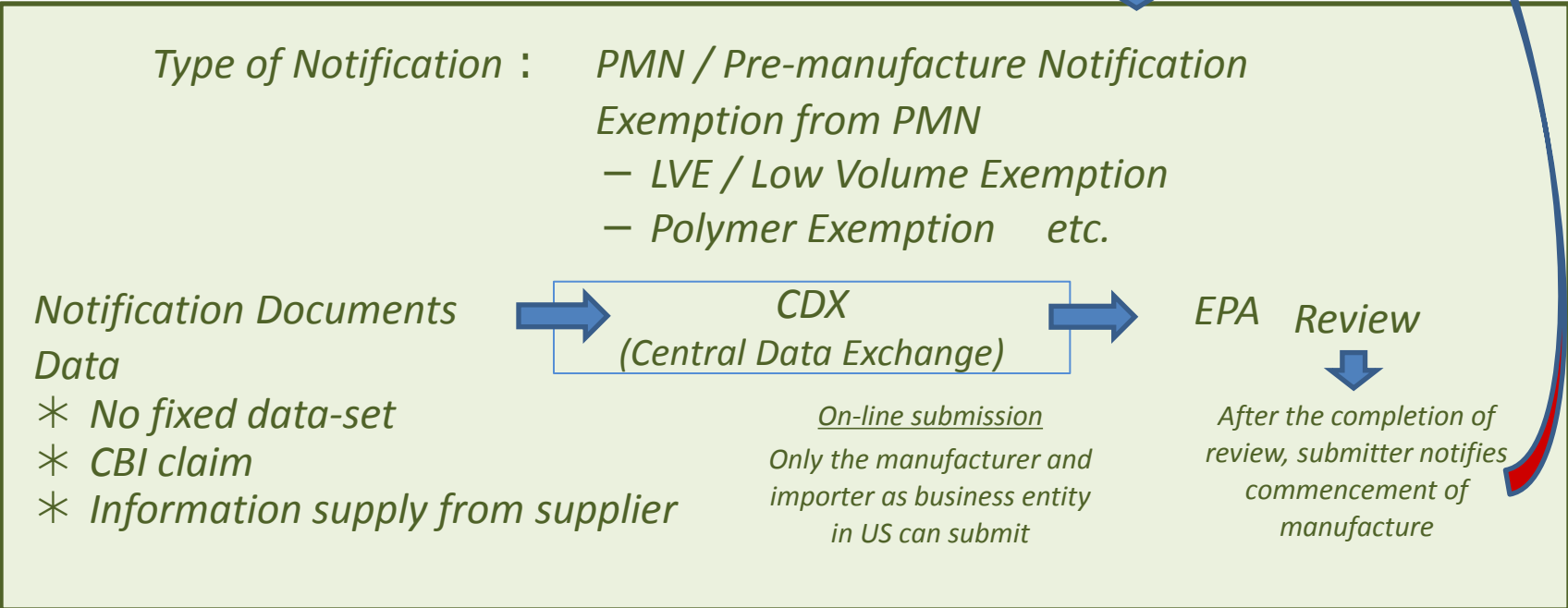
TSCA Inventory
Public Part / Confidential Part (No. of the substance listed as of April, 2018 : 85,000 --- from EPA site)



*Listed : Existing substance
 Can be used (still, refer to the identification)*



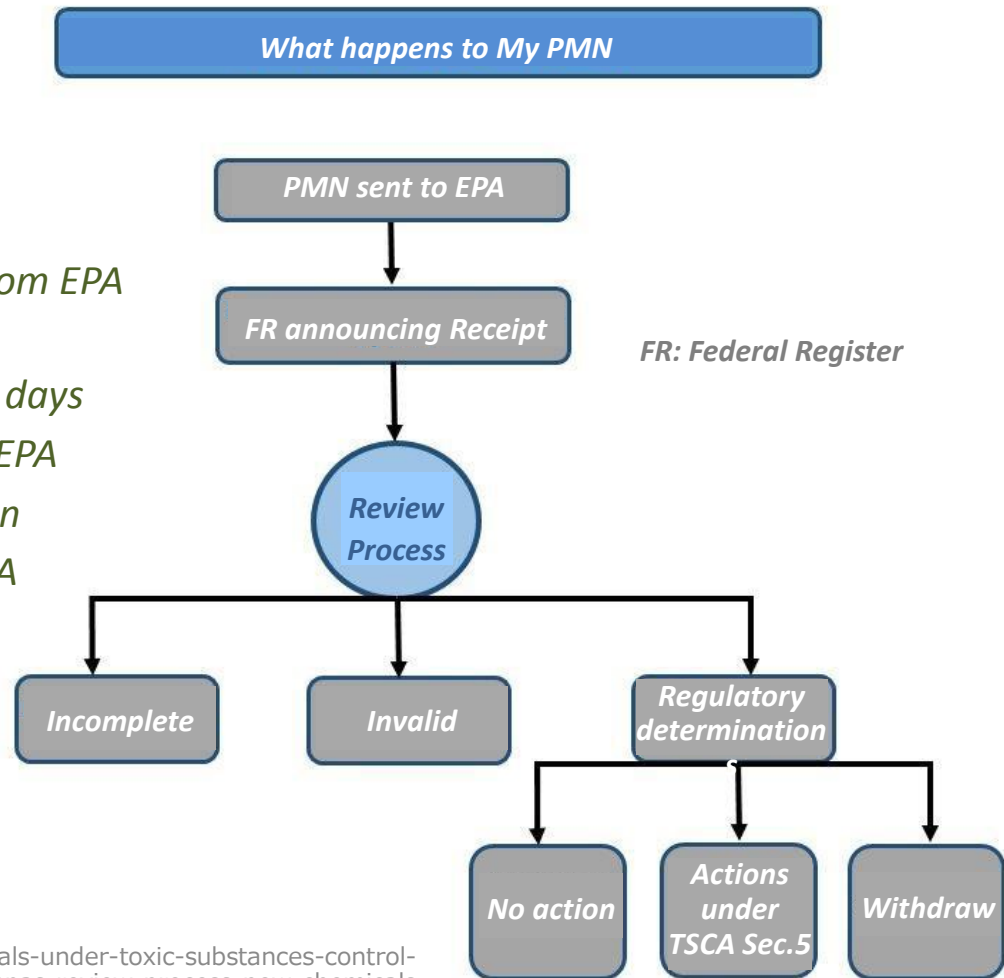
*Not listed: New substance
 Needs to be notified*



TSCA - General Introduction

PMN Flow

1. Submission of PMN to EPA
2. Receipt and Quick review at EPA
3. Notice of commencing Evaluation from EPA
 - Evaluation Period: 90 days
 - Postpone (by EPA): maximum 90 days
 - Notice or inquires possible from EPA
 - may cause delays in evaluation
5. Notice of evaluation results from EPA



<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epas-review-process-new-chemicals>

Amended TSCA

To make chemical management under TSCA more workable...

EPA is required to ...

- re-evaluate existing chemicals listed on the inventory
- promulgate a number of rules to set up the procedures EPA will use to implement, and otherwise align, EPA's chemical management program with the new requirements and responsibilities in the law.

Strengthened EPA's authority...

- (TSCA Sec. 4, 5 &6)
- Data and tests requirements...
 - Regulations ...

Framework Rules

- Active/Inactive Inventory Notification Rule
- Prioritization Rule
- Risk Evaluation Rule
- Fee Rule

Other requirements

- Existing and New Chemicals
- CBI (Confidential Business Information)
- Mercury

Amended TSCA

Active / Inactive Inventory Reporting Rule

- *Final Rule Signed : June 22, 2017*
- *Final Rule published : August 11, 2017*
- *Industry must report on the chemicals they manufactured, and may report on chemicals they processes, in previous 10 years*
- *Chemicals reported will be designated as active*
- *Chemicals not reported will be designated as inactive*
- *Industry must report on the chemicals designated as inactive when they restart or plan to restart commercial activities of that designated substance.*

Reporting will help inform the chemicals EPA prioritizes for risk evaluation.

Amended TSCA

Active / Inactive Inventory Notification Rule

Retrospective Reporting – NOA Form A

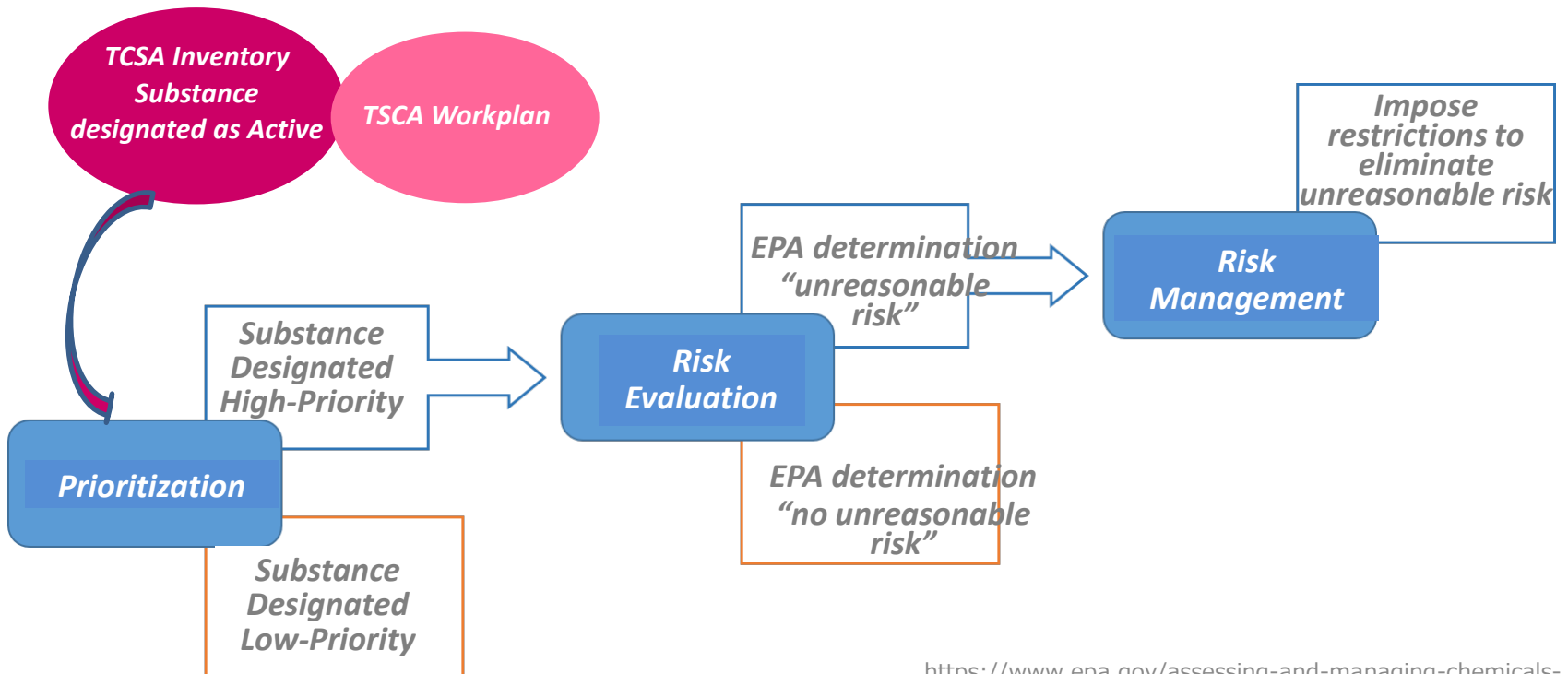
- Who reports? :* Manufacturer / Importer (must), Processor (may)
- What is reported :* Chemical substance listed on TSCA inventory Chemical substances on the TSCA inventory that were in U.S. commerce for non-exempt purposes during 10 years before June 22, 2016
- Reporting period :* Manufacturer / Importer Aug. 12, 2017 – Feb. 7, 2018
Processors who chooses to report Aug. 12, 2017 – Oct. 5, 2018

Future Reporting – NOA Form B

- Who reports? :* Manufacturer, importer and processors (must)
- What is reported :* Chemical substances designated as “inactive” on the TSCA Inventory that are anticipated to be re-introduced into U.S. commerce for non-exempt purpose.
- Reporting period :* prior to re-introduction into U.S. commerce, but not more than 90 days

Amended TSCA

Prioritization and Risk Evaluation Rules



<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#determination>

Amended TSCA

Prioritization Rule

Final Rule Signed : June 22, 2017

High-priority substance : may present an unreasonable risk of injury to health or the environment due to potential hazard and potential route of exposure under the conditions of use (including an unreasonable risk to a “potentially exposed or susceptible subpopulation)

Low-priority substance : does not meet the standard for high-priority, based on information sufficient to establish

*Preference : TSCA Work Plan chemicals (2014 issue, 90 substances)
(List of the substances to be further assessed EPA identified as a part of enhancement of managing existing chemicals)*

Screening criteria : Hazard, Exposure, Persistence, Bioaccumulation, Toxicity, Cancer, etc.

Amended TSCA

Risk Evaluation Rule (Existing substance)

- Determine if a chemical presents an unreasonable risk of injury to health or the environment under condition of use
- Without consideration of cost or other non-risk factors
- Including unreasonable risk of potentially exposed or susceptible subpopulation determined to be relevant to the evaluation

Final Rule Signed : June 22, 2017

Substance to be evaluated :

- High-priority substance
- Work plan Initial 10 substances
- Manufacture Request

Evaluation Period :

3~3.5 years / substance

- 1,4 Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster (HBCD)
- Methylene Chloride
- N-Methylpholidone
- Pigment Violet 29
- Trichloroethylene
- Tetrachloroethylene

5 substances getting expedited action

- Decabromodiphenyl ether (DecaBDE)
- Pentachlorothiophenol (PCTP)
- Phenol, isopropylated, phosphate (3:1)
- Hexachlorobutadine (HCBD)
- 2,4,6-Tris(tert-butyl) phenol

PBT substances on TSCA work plan : Fast-track process, use and exposure assessment required and no formal risk evaluation (unless manufacture requested)

Amended TSCA

Condition of Use

The circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

- *Generally uses that are legacy uses and intentional misuse are not included in the conditions of use*
- *Statutory language for scope “the Administrator expects to consider”*
 - *EPA may exclude from an individual risk evaluation some activities that are conditions of use (e.g. de minimis use that presents low risk)*

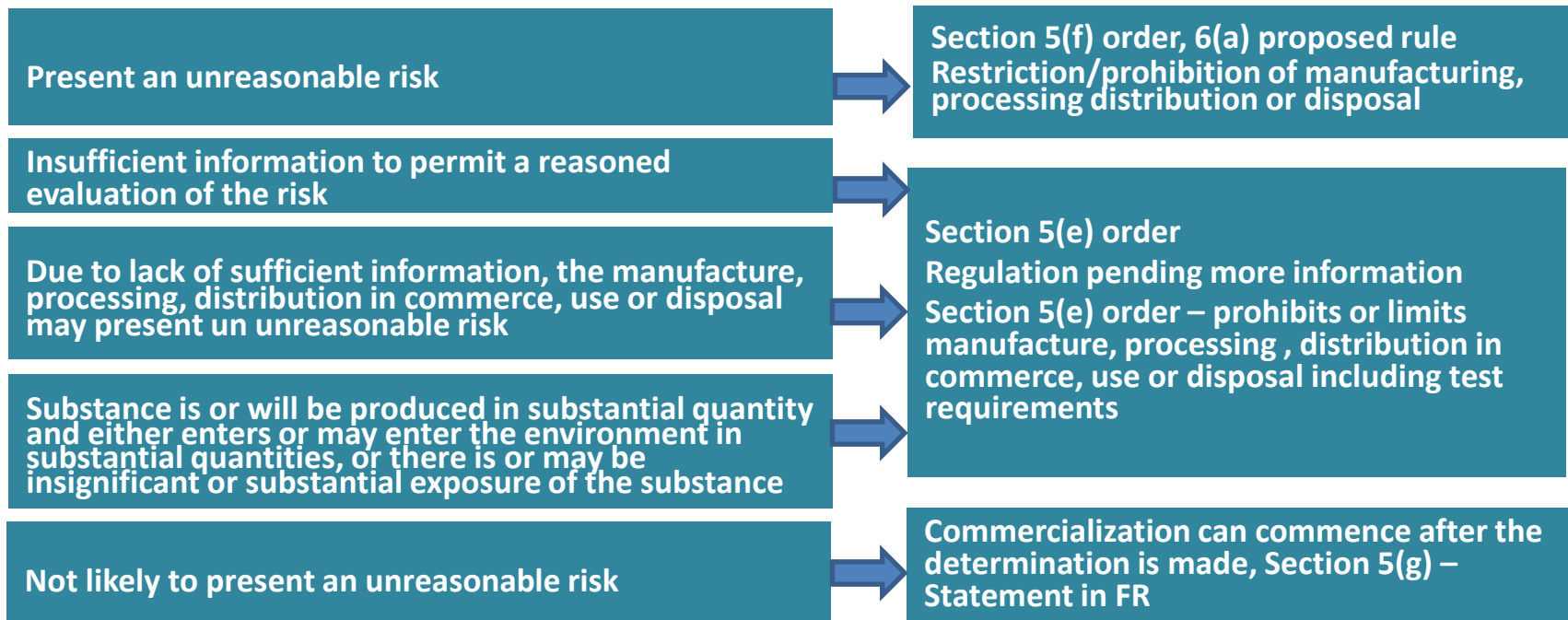
A risk determination will be made for each EPA includes in the risk evaluation

Amended TSCA

Evaluation of New Chemical Substance

EPA

- is required to make an affirmative findings on new chemicals or significant new uses of existing chemicals before those chemicals being launched in the market
- to decide either of the followings by statute after 90 days evaluation period



Amended TSCA

CBI (Confidential Business Information)

*New requirement: Greater public access to critical chemical information
 EPA is required to review CBI claim if it is appropriate or not
 EPA is requested to make new CBI rule*

All CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA --- See CBI Substantiation Template by EPA

- Sunset time: 10 years (can be extended)*
- Review: New CBI claim – Chemical identity 100%
 Other information 25%*



Unique Identifier is assigned to the chemical identity

- *Unique Identifier is applied to other information or submission*
- *Ensure non-confidential information received by EPA identifies the chemical substance using unique identifier while protecting specific chemical identity information*

Amended TSCA

Fee Rule

Note: Small Business – Revenue \$91MM as average annual value over 3 years preceding the date of submission.

Category	Fee (\$US)	Fee(\$US) Small Business
SECTION 4		
Test Order	9,800.00	1,950.00
Test Rule	29,500.00	5,900.00
Enforceable Constant Agreement	22,800.00	4,600.00
SECTION 5		
PMN, SNUN, MACA	16,000.00	2,800.00
LoREX, LVE, TME etc.	4,700.00	940.00
SECTION 6		
EPA-initiated	1,350,000.00	27,000.00
Manufacture-related (Work Plan)	1,300,000.00	1,300,000.00
Manufacture-related (non Work Plan)	2,600,000.00	2,600,000

Prepublication Proposed Rule : From fiscal year 2019 (October 1, 2018)

After publication on Federal Register, collection under new rule will commence

Fees will be adjusted every three years if the amount received would be sufficient to cover 25% of the costs for TSCA 4,5 and 6.

Amended TSCA & Current Status

Evaluation at EPA --- PMN, MCANS, SNUNs, LVE & Other exemptions

Total Cases	1,894
Total Review Completed	1,351
Cases Determined to be Invalid or Incomplete	91
Cases Under review as of April 10, 2018	452

Period : June 22, 2016 –
April 10, 2018

PMN/MCAN/SNUM Review Completed	
Allowed to commercialize with out restrictions – Not likely to present unreasonable risk, TSCA 5(g) notice	122 (≅ 20%)
Allowed to commercialize with restrictions <ul style="list-style-type: none"> - Insufficient information – TSCA 5(e) order & SNUR - May present unreasonable risk –Exposure-based guidelines apply for production greater than 10t/year – TSCA 5(e) order & test at certain production volume 	341 (≅ 54%)
Not allowed to commercialize pending development of information <ul style="list-style-type: none"> - May present unreasonable risk – TSCA5(e), test required before commercialization - Insufficient information – TSCA 5(e) order, test before commercialization 	3
Banned <ul style="list-style-type: none"> - Will present unreasonable risk – TSCA 5(f), 5(f) order or 6)a rule & SNUR 	0
Case withdrawn	170
Total	636

LVE& LoREX Completed	
Exemption Granted	562 (≅ 80%)
Exemption Denied	120
Withdrawn	33
Total	715
NOC	
No received	455

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsc/statistics-new-chemicals-review>

Amended TSCA & Current Status

SNUR

One type of safety determination is that a chemical can be used safely for uses listed in the PMN but that this may not be true for other uses

→ EPA can allow that new chemical to become and existing chemical with limitations

A significant new use rule is a regulation that describes allowed uses of a new chemical and restrictions that manufactures, importer or processors must follow as well as the reporting procedures they have to follow in case of using that chemical substance

→ Under New TSCA, understanding “SNUR” is extremely important

*EPA review of new chemical substance = Affirmatively determine safety → EPA liable in the event that a chemical is found to be unsafe → EPA is being more cautious and only allowing uses and practices where they are comfortable safety can be assured → **SNUR more common***



Significant impact on business

Amended TSCA & Current Status



How to face PMN review & SNUR

- *Ensure all available information on a chemical (tests, literature, models, etc) and include it in a PMN and subsequent SNUN's if any*
- *Be aware of EPA's concerns about classes of chemicals*
- *Confirm your chemical does not included addressed concern in the initial PMN*
- *Consider available literature that addresses concerns and provide references to EPA as part of PMN*
- *Be aware what SNUR are and estimate potential impact on business*
- *Information sharing within supply chain and positive information supply to EPA*
- *Pre-submission consultation with EPA*

Call us immediately!

We, Knoell Group will assist you on every TSCA notifications in perfect manner, from consultation, dossier preparation, submission to inventory listing of your substances.



Thank you so much to be with us today!!

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